Boehringer Ingelheim

March 25, 2021

Boehringer Ingelheim
Animal Health USA Inc.

www.boehringer-ingelheim.us

Leann McAlister
3239 Satellite Blvd.
Duluth, GA 30096

Attn: Robert Miller
VIA CDX PORTAL
Document Processing Desk – 6(a)(2)
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-3553

SUBJECT: Resubmission of all 2018 and 2019 FIFRA Section 6(a)(2) Aggregate Incident Reports for Frontline Spot-On Products

Per your request during our meeting on March 24, 2021, we are resubmitting all of the EPA Quarterly Aggregate Reports for 2018 and 2019 in support of EPA's preparation for a congressional inquiry into all spot-on pet products resulting from the recent Seresto collar articles.

Please note that all of these reports have been previously submitted via hard copy to include both Merial, Inc. and Boehringer Ingelheim Animal Health USA Inc.

If you have any questions regarding this report, please contact me at 678-638-3701 or via email at leann.mcalister@boehringer-ingelheim.com.

Sincerely,

Leann McAlister

Leann McAlister
Regulatory Affairs

Enclosure

Boehringer Ingelheim

January 28, 2020

Boehringer Ingelheim
Animal Health USA Inc.

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SUBJECT: FIFRA Section 6(a)(2) Aggregate Incident Reports for 4Q19 (01Oct2019 through 31Dec2019)
Human and Domestic Animals in the US and Extraterritorial
Associated with the Following Boehringer Ingelheim Registrations:

- FRONTLINE® Spray, EPA Reg. No. 65331-1
- FIPAIRA® for Cats, EPA Reg. No. 65331-2
- FIPAIRA® for Dogs, EPA Reg. No. 65331-3
- FRONTLINE® Plus for Cats, EPA Reg. No. 65331-4
- FRONTLINE® Plus for Dogs, EPA Reg. No. 65331-5
- FRONTLINE® Active for Dogs, EPA Reg. No. 65331-9

Please find enclosed the FIFRA 6(a)(2) Aggregate Incident Report for 4Q19, submitted in duplicate per the EPA's request on 30Nov12. Aggregate reports for humans (HD/HE: Minor/Unknown) and domestic animals are submitted quarterly. This report is also being provided as a .pdf file on CD-ROM per EPA's communication on 03Sept14. Since these products are produced and sold worldwide, Boehringer Ingelheim is providing worldwide reporting of adverse events for the aforementioned products.

If you have any questions regarding this report, please contact me at 678-638-3701 or via email at leann.mcalister@boehringer-ingelheim.com.

Sincerely,

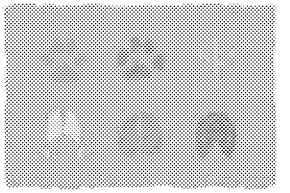
Leann McAlister

Leann McAlister
Regulatory Affairs

Enclosures

FRONTLINE BRAND PRODUCTS

EPA Quarterly Aggregate Report



Number of Incidents and Adverse Effects Reported by Exposure Type and Severity Category (USA)
Reporting Period: 01-Oct-2019 to 31-Dec-2019
Product Family: Frontline Products (include non-specific)

Generic Name / USA Registration Number	Total Incidents	H-D Human - Minor Effects	H-E Human - Unknown, Unspecified or Delayed Effects	D-A Domestic Animal - Death	D-B Domestic Animal - Major Effects	D-C, D-D, D-E Domestic Animal - Moderate, Minor, Unknown or Unspecified
FIPRONIL 10%/S METHOPRENE 12% SPOT ON / 65331-4	437	7	4	19	5	402
FIPRONIL 10%/S METHOPRENE 9% SPOT ON / 65331-5	762	3	21	27	13	698
FIPRONIL SPRAY / 65331-1	13	0	0	0	1	12
Totals	**1,212**	**10**	**25**	**46**	**19**	**1,112**

USA Off-label species totals are included

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
Collection of an AE report does not constitute an admission by BIAH that out product caused or contributed to the AE.
Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014391-00004

Use in Off-Label Species (USA)
Reporting Period: 01-Oct-2019 to 31-Dec-2019
Product Family: Frontline Products (include non-specific)

Generic Name / Registration Number Species	Total Incidents	D-A Domestic Animal - Death	D-B Domestic Animal - Major Effects	D-C, D-D, D-E Domestic Animal - Moderate, Minor, Unknown or Unspecified
FIPRONIL 10%/S METHOPRENE 9% SPOT ON / 65331-5	3	0	1	2
Feline	3	0	1	2
Totals	**3**	**0**	**1**	**2**

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
Collection of an AE report does not constitute an admission by BIAH that out product caused or contributed to the AE.
Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014391-00005

Number of Incidents and Adverse Effects Reported by Exposure Type and Severity Category (Extraterritorial)
Reporting Period: 01-Oct-2019 to 31-Dec-2019
Product Family: Frontline Products (include non-specific)

Generic Name / USA Registration Number	Total Incidents	H-D Human - Minor Effects	H-E Human - Unknown, Unspecified or Delayed Effects	D-A Domestic Animal - Death	D-B Domestic Animal - Major Effects	D-C, D-D, D-E Domestic Animal - Moderate, Minor, Unknown or Unspecified
FIPRONIL 10%/S METHOPRENE 12% SPOT ON / 65331-4	201	0	0	4	3	194
FIPRONIL 10%/S METHOPRENE 9% SPOT ON / 65331-5	298	0	0	1	8	289
FIPRONIL SPOT ON CAT / 65331-2	112	3	0	3	4	102
FIPRONIL SPOT ON DOG / 65331-3	139	0	0	2	6	131
FIPRONIL SPRAY / 65331-1	157	4	0	11	3	139
Totals	**907**	**7**	**0**	**21**	**24**	**855**

Extraterritorial Off-label species totals are included

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ED_005739D_00014391-00006

Use in Off-Label Species (Extraterritorial)
Reporting Period: 01-Oct-2019 to 31-Dec-2019
Product Family: Frontline Products (include non-specific)

Country Generic Name / USA Registration Number Species	Total Incidents	D-A Domestic Animal - Death	D-B Domestic Animal - Major Effects	D-C, D-D, D-E Domestic Animal - Moderate, Minor, Unknown or Unspecified
FIPRONIL 10%/S METHOPRENE 9% SPOT ON / 65331-5	2	0	0	2
Feline	2	0	0	2
FIPRONIL SPOT ON CAT / 65331-2	2	1	1	0
Rabbit	2	1	1	0
FIPRONIL SPOT ON DOG / 65331-3	4	0	2	2
Feline	4	0	2	2
FIPRONIL SPRAY / 65331-1	2	0	2	0
Hedgehog	1	0	1	0
Rabbit	1	0	1	0
Totals	**10**	**1**	**5**	**4**

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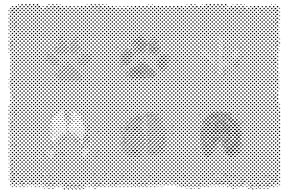
ED_005739D_00014391-00007

EPA Report



Worldwide Adverse Event Reports Involving - Animal Cases
Reporting Period: 01-Oct-2019 to 31-Dec-2019

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
30-Oct-2019	UAE; 19AR000032; Buenos Aires; Argentina	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** - **Age:** 1.00 Year(s) **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** SC-subcutaneous **Was the product used ok?:** No (Overdose)	22-Oct-2019	22-Oct-2019	0 Day(s)	D-D	On 29 October 2019, an attending vet reported an Suspicion of Lack of Efficacy: name Futilla, from 1 to 2 year old, female sex, weight 8 kg, intact, received FRONTLINE SPOT ON 10-20 KG., batch 022/16 , expiry Oct/19, topical, on 22 October and 72 hours after product administration the animal continues having ticks.
13-Nov-2019	UAE; 19AR000035; Argentina; Argentina	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** - **Age:** 1.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Nov-2019	04-Nov-2019	0 Day(s)	D-D	On 12 November, the reported by owner, Pipi, 1 to 2 year old, unknown weight, feline, mixed breed, good reproductive status, received FRONTLINE PLUS CAT, batch unknown, expiry unknown, SC route, 0,50 ML dose, administered by owner on 4 November 2019 1 days after product administration, the animal continues having fleas. The last time she used Frontline cat was between the month August. He does not make environmental treatment.
10-Dec-2019	UAE; 19AR000039; San Isidro, Buenos Aires, Argentina; Argentina	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 6 - 7 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Nov-2019	29-Nov-2019	0 Day(s)	D-D	On 9 December, the reported by owner, Feijoada, 4 year old, 6 to 7 kg, feline, mixed breed, good reproductive status, received FRONTLINE PLUS CAT , batch unknown, expiry unknown, SC route , 0,50 ML dose, administered by owner on 29 November 2019 1 days after product administration, the animal continues having fleas. He does not make environmental treatment,

N/A signifies the information for this field is either not available or not applicable

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* indicates Approximate date or weight.

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ED_005739D_00014391-00008

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
10-Dec-2019	UAE; 19AR000040; -; Argentina	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** - **Age:** 9.00 Year(s) **Weight:** 40 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Dec-2019	04-Dec-2019	0 Day(s)	D-B	On 9 December 2019 ,an animal owner reported an adverse event, Manson, 9 years old, 40 kg , intact, canine, Golden Retriever, in good health status, received FRONTLINE PLUS 20-40 KG , batch 001/18A , expiry date 12 December 2020 , topical, dose 2.68 ML. 8 hours after product administration, the animal had a convulsion, the owner gave 1 tablet of Phenobarbital x 60 mgr and 3 hours and a half had another convulsion. That is the second time this has happened, after application of Frontline Plus a few months ago (Was not reported).
02-Oct-2019	UAE; 19AU001042; QLD; Australia	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 5.83 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	21-Sep-2019*	01-Oct-2019	10 Day(s)	D-D	As reported by the veterinary nurse, Jerry a 5.83 kg, 13 year old, male neutered, domestic short hair cat was treated topically with FRONTLINE SPRAY (2.5g/L fipronil, batch and expiry unknown) dose rate unknown by the owner for flea and tick prevention on an unknown date (estimated as 21 SEP 2019 for reporting purposes). The owner applies product every 2 weeks. Note FRONTLINE SPRAY is applied every 3 weeks for tick control. On 1 OCT 2019 the cat presented to the clinic with an engorged tick (tick species unknown), the cat was off food and flat. The cat was treated with tick anti-toxin serum and remains under treatment at the time of reporting. This is the extent of the information available.
16-Oct-2019	UAE; 19AU001114; ACT; Australia	**Species:** Canine **Breed:** Cavalier King Charles **Sex:** M **Sex qualifier:** Unknown **Age:** 6.50 Year(s) **Weight:** 9.00 kg	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	09-Oct-2019	15-Oct-2019	6 Day(s)	D-C	As reported by the owner, Leroy a 6 year 6 month old, 9kg, male Cavalier King Charles was applied topically one dose unit of FRONTLINE PLUS DOG M (1.34ml, 100g/L Fipronil 90g/L (S)-methoprene, BA: S60802AL and EXP: 03/2021) by the owner for flea and tick control on 9 OCT 2019. It is noted that the M dog product pack size is label indicated for dogs 10 to 20 kg bodyweight. On 15 OCT 2019, the animal displayed signs of tick paralysis (lethargy, weakness in hind legs and nausea). The following day, the owner found and removed a tick, veterinary treatment was sought on 16 OCT 2019. A full clip and tick examination was performed, where another tick was found (identified as a paralysis tick by consulting vet) and two tick craters. The vet noted that the dog experienced multiple vomits following the vet examination. It is unknown whether the tick was engorged at the time of identification. The animal was given intravenous fluids, AVSL Ixodes Holocyclus Antivenom, 0.9ml Cerenia injection (maropitant) and 0.45ml Clavulox (amoxicillin plus clavulanic acid) injection. At the time of reporting, the outcome is unknown. This is the extent of the information available. UPDATE 25 OCT 2019 As reported by the attending veterinarian, the animal was reassessed 23 OCT 2019 and considered recovered on this date. This is the extent of the information available.
17-Oct-2019	UAE; 19AU001115; -; Australia	**Species:** Canine **Breed:** Collie **Sex:** M **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** Advantix	01-Sep-2019	12-Sep-2019	11 Day(s)	D-B	As reported by the owner, Kodi, an 8 yr old, 23 kg, male neutered, Border Collie cross Kelpie, was applied one dosage form topically of FRONTLINE ORIGINAL FOR DOGS 20- 40 kg (100 g/L fipronil, batch and expiry unknown) by the owner for flea and tick treatment on 01 SEP 2019. The owner reported that the dog had been receiving the product for approx. 4 years but the frequency was not

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ED_005739D_00014391-00009

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 8.00 Year(s) **Weight:** 23 kg				(imidacloprid and permethrin); **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					specified. On 12 SEP 2019 the animal was diagnosed with tick paralysis. Treatment with tick antiserum and supportive care was provided and Kodi was discharged on 13 SEP 2019. It should be noted that the vet history states that the dog received Advantix (imidacloprid and permethrin) on the first of every month, however this was not mentioned in the report from the animal owner. This is the extent of the information available.
24-Oct-2019	UAE; 19AU001160; NSW; Australia	**Species:** Canine **Breed:** Silky Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 3.50 Year(s) **Weight:** 6.0 kg	2	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)	19-Oct-2019	22-Oct-2019	3 Day(s)	D-D	As reported by the owner, Clancy a 3 year 6 month old, 6kg, male Australian Silky Terrier was treated topically with 'around 20 pumps' of FRONTLINE SPRAY (2.5g/L, product unsubstantiated, bottle size unknown) by the owner for parasite control on 19 OCT 2019. As the bottle size is unknown, the mL/kg dose and the mg fipronil/kg dose is not able to be calculated. However the labelled dose rate for a 6 kg dog for a paralysis tick claim is 12 spray pumps per kg for the 100 mL bottle (which equates to 72 pumps for a 6 kg dog), or 4 spray pumps per kg for the 250 mL and 500 mL bottles (which equates to 24 pumps for a 6 kg dog). Therefore 20 pumps represents an underdose of product for a paralysis tick claim in a 6 kg dog. On 22 OCT 2019, a small, live paralysis tick was found burying into the animal's neck, note the tick was not engorged. The tick was removed by the owner using a tick freeze spray (brand name unknown) and tick twisters. The animal displayed no signs of tick paralysis. No veterinary treatment was sought and the animal was considered recovered the same day. It should be noted that on 07 AUG 2019, the animal was administered the same dose of FRONTLINE SPRAY. On 28 AUG 2019, a slightly engorged, dead paralysis tick was found on the animal within the same neck region. The tick was removed in an identical manner by the owner, the animal did not display any signs of tick paralysis. No veterinary treatment was sought and the animal was considered recovered the same day. This is the extent of the information available.
24-Oct-2019	UAE; 19AU001164; VIC; Australia	**Species:** Canine **Breed:** Boxer **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 23 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Oct-2018*	22-Oct-2018*	N/A	D-D	As reported by the owner, Tessa a 4 year old, 23kg, female neutered, Boxer was applied topically one dose unit of FRONTLINE PLUS FOR DOGS 20-40kg (2.68ml, 100g/L Fipronil, 90g/L (S)-methoprene, batch and expiry unknown) by the owner for flea and tick treatment on 22 OCT 2019. On the 22 OCT 2019 the owner noticed 'a few small baby fleas emerging'. It should be noted that small fleas have been seen after every application in the last 12 months, adult fleas were not seen. It is unknown if veterinary attention was sought and the condition is ongoing at the time of reporting. This is the extent of the information available.
24-Oct-2019	UAE; 19AU001165; QLD; Australia	**Species:** Canine **Breed:** Border Collie **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	21-Aug-2019	21-Aug-2019	N/A	D-D	As reported by the owner, two Border Collies (signalments otherwise unknown) were each administered 2.68 mL (1 pipette) of FRONTLINE PLUS L DOG (batch and expiry unknown) by the owner for parasite control on 21 AUG 2019, 21 SEP 2019 and 21 OCT 2019. On all occasions, adult fleas and flea dirt were still present on both animals, with the owner reporting that there was no change in the flea population. The animals also experienced skin irritation from excessive scratching. No veterinary treatment was sought. At the time of reporting, the condition is ongoing. It

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Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** Unknown to Company					should be noted that the owner has four other animals, two small canines and two felines in the same household i.e. six in total. Whilst the small canines were administered FRONTLINE PLUS S DOG on the same listed dates, the administration dates and quantity for the felines in relation to FRONTLINE PLUS CAT are uncertain. Therefore, it is unknown whether the products were used correctly throughout the entire household. Refer to 19AU001166 and 19AU001167. This is the extent of the information available.
24-Oct-2019	UAE; 19AU001166; QLD; Australia	**Species:** Canine **Breed:** Canine various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	21-Aug-2019	21-Aug-2019	N/A	D-D	As reported by the owner, one Toy Poodle and one small canine (signalments otherwise unknown) were each administered 0.67 mL (1 pipette) of FRONTLINE PLUS S DOG (batch S61717AL and expiry JUNE 2021) by the owner for parasite control on 21 AUG 2019, 21 SEP 2019 and 21 OCT 2019. On all occasions, adult fleas and flea dirt were still present on both animals, with the owner reporting that there was no change in the flea population. The animals also experienced skin irritation from excessive scratching. No veterinary treatment was sought. At the time of reporting, the outcome is ongoing. It should be noted that the owner has four other animals,two Border Collies and two felines in the same household i.e. six in total. Whilst the Border Collies were administered FRONTLINE PLUS L DOG on the same listed dates, the administration dates and quantity for the felines in relation to FRONTLINE PLUS CAT are uncertain. Therefore, it is unknown whether the products were used correctly throughout the entire household. Refer to 19AU001165 and 19AU001167. This is the extent of the information available.
24-Oct-2019	UAE; 19AU001167; QLD; Australia	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	21-Oct-2019*	21-Oct-2019*	0 Day(s)	D-D	As reported by the owner, two felines (signalments otherwise unknown) were each administered an unknown amount of FRONTLINE PLUS CATS (batch and expiry unknown) by the owner for parasite control on 21 OCT 2019. It is unknown whether the animals received the product previously. At the time of reporting, adult fleas and flea dirt were still present on both animals, with the owner reporting that there was no change in the flea population. The animals also experienced skin irritation from excessive scratching. No veterinary treatment was sought and the outcome is ongoing. It should be noted that the owner has four other animals, two Border Collies and two small canines in the same household, which were administered FRONTLINE PLUS DOGS on 21 AUG 2019, 21 SEP 2019 and 21 OCT 2019. Refer to 19AU001165 and 19AU001166. This is the extent of the information available.
04-Nov-2019	UAE; 19AU001213; -; Australia	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Oct-2019	04-Nov-2019	10 Day(s)	D-B	As reported by the owner, Ralphie a 7 year old, 8kg, male neutered Jack Russell was applied 0.67 ml (one pipette) of FRONTLINE PLUS S DOG (100g/L Fipronil, 90g/L (S)-methoprene, batch and expiry unknown) by the owner for flea and tick control on 25 OCT 2019. On the 4 NOV 2019, a paralysis tick was found on the dog's neck. The dog was displaying symptoms of tick paralysis including voice changes and wobbly hind legs. The dog presented at a veterinary clinic on 4 NOV 2019 and a veterinary examination was performed, the vet noted that the tick had been engorged for approximately 24 hours. The dog was hospitalised and treated with tick anti-serum and was discharged on 5 NOV 2019. At the time of reporting the condition is ongoing. This is the extent of the information available.

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ED_005739D_00014391-00011

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
07-Nov-2019	UAE; 19AU001226; -; Australia	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 6.5 kg*	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Nov-2019	03-Nov-2019*	2 Day(s)	D-D	As reported by the owner, Ruby a 11 year old, approximately 6.5kg, female neutered Jack Russel X was applied one dose unit of FRONTLINE ORIGINAL FOR SMALL DOGS (100g/L Fipronil, BA: F20911AX, EXP: 06/2021) by the owner for flea and tick control on 1 NOV 2019. On approximately 3 NOV 2019, the owner noted that the dog was intensely scratching at the site of application. Later that day the skin was red at the application site. At the time of reporting the dog was scheduled to see a vet, it is unknown if veterinary treatment was required. The condition is still ongoing. This is the extent of the information available.
08-Nov-2019	UAE; 19AU001227; -; Australia	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2019*	01-Feb-2019*	31 Day(s)	D-B	As reported on social media by a shelter, an unknown number of pups (estimated as 2, further signalment not provided) received FRONTLINE (product unsubstantiated, batch and expiry unknown) on an unknown date (estimated as 1 JAN 2019 for reporting purposes) by unknown individuals via an unknown method at an unknown dose. At an unknown time period afterwards (estimated a 1 FEB 2019 for reporting purposes) the dogs experienced seizures. It is unknown if it was treated and the outcome is unknown. This is the extent of the information available.
15-Nov-2019	UAE; 19AU001253; NSW; Australia	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 19 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	08-Nov-2019*	11-Nov-2019*	3 Day(s)	D-B	As reported by the owner, a 19kg, female canine (signalment otherwise not disclosed) was applied topically one dose unit of FRONTLINE ORIGINAL (product unsubstantiated, product weight range unknown) by the owner for flea and tick control on an unknown date, estimated as 8 NOV 2019 for reporting purposes. Approximately three days after product application, the owner found an engorged tick (tick species unknown, details otherwise unknown) and veterinary treatment was sought. The clinical signs were not provided by the owner, the dog was treated for suspected tick paralysis (treatment details unknown). At the time of reporting, the animal had recovered. It should be noted that on an unknown date previously (estimated as 2-3 years ago), the animal received veterinary treatment for suspected tick paralysis after a 'monthly application' of 'Advocate' (product unsubstantiated- imidacloprid plus moxidectin) and recovered on an unknown date. This is the extent of the information available.
15-Nov-2019	UAE; 19AU001264; -; Australia	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	07-Nov-2019*	14-Nov-2019*	1 Week(s)	D-D	As reported by the owner, a male canine (signalment otherwise not disclosed) was applied topically one dose unit of FRONTLINE PLUS FOR DOGS UP TO 10KG (0.67ml, 100g/L Fipronil 90g/L (S)-methoprene, batch and expiry unknown) by the owner for flea and tick control on approximately 7 NOV 2019. On an unknown date, the owner noticed an increase in the number of fleas within the environment and on the animal. The owner reported that the product did not get rid of the fleas on her animal and the fleas were causing the dog to scratch. It is unclear if the dog has received monthly flea treatments or if the product was used correctly. No veterinary treatment was sought and at the time of reporting, the outcome is ongoing. This is the extent of the information available.
18-Nov-2019	UAE; 19AU001267; QLD; Australia	**Species:** Canine **Breed:** American Staffordshire	1	1	0	**Product used:** FIPRONIL 10%/S	20-Oct-2019*	17-Nov-2019	1 Day(s)	D-D	As reported by the Owner, Sasha an approx. 35 kg, Female American Staffordshire Terrirer (signalment otherwise unknown) was applied topically one dose unit of FRONTLINE PLUS FOR

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ED_005739D_00014391-00012

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 35 kg*				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					LARGE DOGS 20-40kg (2.68ml, 100g/L Fipronil 90g/L (S)-methoprene, batch and expiry unknown) by the owner for flea and tick control on approximately 20 OCT 2019 and a second time on 16 NOV 2019. The owner noticed fleas were still present on the animal and in the environment following both treatments. The owner has made the dog sleep outside due to level of flea infestation. No veterinary treatment was sought and the condition is ongoing at the time of reporting. The owner advised that the dog was washed with a flea control shampoo (product name unknown) two days prior and two days after both administrations. This is the extent of the information available.
20-Nov-2019	UAE; 19AU001268; -; Australia	**Species:** Canine **Breed:** Rottweiler **Sex:** M **Sex qualifier:** - **Age:** 7.00 Year(s) **Weight:** 53 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Sep-2019*	11-Sep-2019*	N/A	D-D	As reported by the owner, Tyson a 7 year old, 53 kg, male intact Rottweiler was applied topically one dose unit of FRONTLINE PLUS FOR EXTRA LARGE DOGS 40-60kg (4.02ml, 100g/L Fipronil 90g/L (S)-methoprene, BA: R61306AR, EXP: 05/2020) by the owner for flea control monthly since approximately 11 SEP 2019 with the most recent dose applied on 11 NOV 2019. On 19 NOV 2019 the owner noted that a significant amount of fleas were still present on the animal and felt there was no improvement in flea activity in the last 3 months of application. No veterinary treatment was sought and the condition is ongoing at the time of reporting. This is the extent of the information available.
18-Nov-2019	UAE; 19AU001269; VIC; Australia	**Species:** Feline **Breed:** Burmese **Sex:** F **Sex qualifier:** Neutered **Age:** 15.00 Year(s) **Weight:** 8.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Nov-2019	18-Nov-2019	1 Day(s)	D-D	As reported by the owner, Pepper a 15 year old, 8.5kg, female desexed Burmese cross was administered one dose unit topical of FRONTLINE PLUS FOR CATS (0.5ml, 100g/L Fipronil 120g/L (S)-methoprene. Batch and expiry unknown) given by owner for flea control on 17 NOV 2019. Approx 12 hours later the owner noticed hairloss at the site of application on the cat. No veterinary treatment was sought. It should be noted the animal has received the product before with no known ill effects. The outcome is ongoing at the time of reporting. This is the extent of the information available.
21-Nov-2019	UAE; 19AU001282; NSW; Australia	**Species:** Canine **Breed:** Maltese **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jan-2019*	02-Jan-2019*	1 Day(s)	D-B	As reported by the attending veterinarian, a Maltese dog received FRONTLINE PLUS (product unsubstantiated, product size unknown, batch and expiry unknown) topically for parasite control on an unknown date estimated as 1 JAN 2019 for reporting purposes. Dog had seizures after given the product, time to onset unknown (estimated as 2 JAN 2019) which 'wear off after the medication wears off'. Estimated recovery date 15 JAN 2019. This is the extent of the information available.
03-Dec-2019	UAE; 19AU001302; QLD; Australia	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed)	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products**	27-Nov-2019	28-Nov-2019	1 Day(s)	D-C	As reported by the owner, Tiger an 8 year old, Female Desexed Domestic Shorthair was applied topically one dose unit of FRONTLINE ORIGINAL FOR CATS (0.5ml, 100g/L Fipronil, BA: T21213AX and EXP: 05/2022) by the owner for flea control on the

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ED_005739D_00014391-00013

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** Unknown				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					27 NOV 2019. The following day (estimated as within 12 hours for reporting purposes), the animal experienced hairloss, described as being 5cm in diameter at the application site. Upon further inspection by the owner, it was noticed that the skin appeared 'burnt' and 'red raw'. No veterinary treatment was sought and at the time of reporting, the condition is ongoing. This is the extent of the information available.
02-Dec-2019	UAE; 19AU001333; -; Australia	**Species:** Canine **Breed:** Staffordshire Terrier (American) **Sex:** M **Sex qualifier:** - **Age:** 9.00 Week(s) **Weight:** 5 kg*	1	1	1	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)	28-Nov-2019	28-Nov-2019	0 Day(s)	D-A	As reported by the owner/breeder, a 9 week old, approx. 5 kg, male intact American Staffordshire Terrier X Labrador Retriever was treated topically with FRONTLINE SPRAY (2.5g/L fipronil, batch and expiry unknown) dosed at 0.75mg/kg by the owner for flea and tick prevention on the 28 NOV 2019. Note that this is a very low dose compared to the approved dose rate (by a factor of 20). Within a few hours, the animal experienced vomiting, diarrhoea and inappetence. The severity of the vomiting increased over the following two days and resulted in death on approx. 30 NOV 2019. No veterinary treatment was sought. It should be noted that the mother of this puppy was also treated with an unknown dose of FRONTLINE SPRAY at the same time with no adverse reaction. The owner confirmed no other puppies from the same litter were treated with Frontline Spray and appeared to be healthy at the time of reporting. This is the extent of the information available.
04-Dec-2019	UAE; 19AU001334; NSW; Australia	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 3.7 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Nov-2019	28-Nov-2019	0 Day(s)	D-D	As reported by the owner, Millie and Charlie, two Chihuahuas, approx 5 year old sisters, both 3.7 kg were applied topically one dose unit per animal of FRONTLINE PLUS DOG S (0.67ml, 100g/L Fipronil 90 g/L (S)-methoprene, BA: S63210AL and EXP: 10/2021) by the owner for flea and tick control on the 28 NOV 2019. The same day at an unknown time, the dogs began scratching and 'four or five small live fleas' were found by the owner on each dog. No veterinary treatment was sought and at the time of reporting, the condition is ongoing. It should be noted that whilst the owner has used this product since approx 01 MAY 2015, the frequency of administration and dosage is unknown. The owner advised treatment is often stopped during the winter months due to the lack of fleas present in the environment and additionally, for an unknown period of time, the FRONTLINE PLUS DOG S pipettes were 'split' between the dogs. It should be noted for reporting purposes that the dogs were recently on a course of prednisone for skin allergies, the owner noted that the prednisone was stopped on an unknown date as the scratching was flea related. This is the extent of the information available.
06-Dec-2019	UAE; 19AU001351; NSW; Australia	**Species:** Canine **Breed:** Pug **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 13 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	22-Nov-2019	22-Nov-2019	0 Day(s)	D-D	As reported by the owner, Rufus a 6 year old, 13 kg, Male Pug (signalment otherwise unknown) was applied topically one dose unit of FRONTLINE PLUS DOG M (1.34ml, 100g/L Fipronil 90g/L (S)-methoprene, batch and expiry unknown) by the owner to treat pruritus caused by a suspected mite infestation on 22 NOV 2019. The owner initially reported that the dog had ear mites but later advised she believed it was sarcoptic mange. No veterinary assessment or diagnosis had been made. Please note that the product is not registered to treat ear mites. The pruritus did not improve after the product was applied. The condition is ongoing at the time of reporting. See linked case AUS-BIAHPV1P-18AU001353. This is the extent of the information available.

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ED_005739D_00014391-00014

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
06-Dec-2019	UAE; 19AU001353; NSW; Australia	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Indication not indicated / recommended)	22-Nov-2019	22-Nov-2019	0 Day(s)	D-D	As reported by the owner, Harley a 3 year old, 8 kg, Male Domestic Shorthair (signalment otherwise unknown) was applied topically one dose unit of FRONTLINE PLUS FOR CATS (0.5mL, 100g/L Fipronil 120g/L (S)-methoprene, batch and expiry unknown) by the owner to treat pruritus caused by a suspected mite infestation on 22 NOV 2019. The owner initially reported that the cat had ear mites but later advised she believed it was sarcoptic mange. No veterinary assessment or diagnosis had been made. Please note that the product is not registerd to treat ear mites or sarcoptic mange. The pruritus did not improve after the product was applied. The condition is ongoing at the time of reporting. A dog on the same property had a similar reaction, reported as 19AU001351 (worldwide case #AUS-BIAHPV1P-19AU001353). This is the extent of the information available.
09-Dec-2019	UAE; 19AU001359; NSW; Australia	**Species:** Canine **Breed:** Chihuahua **Sex:** U **Sex qualifier:** Unknown **Age:** 10.00 Week(s) **Weight:** 300 gms	1	1	1	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	07-Dec-2019*	08-Dec-2019*	1 Day(s)	D-A	As reported by the retail outlet, a 10 week old, 300 gram Chihuahua was treated with "small sized Frontline" (product unsubstantiated, product weight range unknown) by the breeder for parasite control on an unknown date (estimated as 07 DEC 2019 for reporting purposes). After an unknown time, the animal died. It is unknown if veterinary treatment was sought. This is the extent of the information available.
17-Dec-2019	UAE; 19AU001380; NSW; Australia	**Species:** Canine **Breed:** Mastiff **Sex:** M **Sex qualifier:** - **Age:** 2.00 Year(s) **Weight:** 25 - 39 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Dec-2019	17-Dec-2019	1 Week(s)	D-D	As reported by the owner, Tiger a 3 year old, 39kg, male intact Mastiff X and Pirate a 2 year old, 25kg, male intact Mastiff X were each applied topically one dose unit of FRONTLINE PLUS FOR LARGE DOGS 20-40kg (2.68ml, 100g/L Fipronil 90g/L (S)-methoprene, BA: S61301AR and EXP: 04/2021) by the owner for flea and tick control on 10 DEC 2019. Since the application on the 10 DEC 2019, the owner has found a lot of adult fleas on both dogs. The owner has applied Frontline Plus to each dog on a monthly basis for multiple years. The owner noted that this is the first time that he has noticed a flea burden. No veterinary treatment has been sought and the condition is ongoing at the time of reporting. This is the extent of the information available.
10-Oct-2019	UAE; 19BE000139; -; Belgium	**Species:** Feline **Breed:** - **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** PO-Oral **Was the product used ok?:** No (Route not indicated / recommended)	09-Jul-2019	09-Jul-2019	N/A	D-D	Poison Centre: call from an animal owner on 9/07/2019 concerning a cat showing vomiting after oral exposure to FRONTLINE spot-on katten. The product was administered orally (medication error).
28-Oct-2019	UAE; 19BE000145;	**Species:** Feline **Breed:** -	1	1	0	**Product used:** FIPRONIL	02-Aug-2019	03-Aug-2019	N/A	D-C	Poison Centre: call from a vet on 3/08/2019 concerning a cat showing tremor after ingestion of 1 pill of MILBEMAX filmomhulde

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	-; Belgium	**Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				10%/S METHOPRENE 12% SPOT ON **Other products used:** MILBEMAX filmomhulde tabl katten; COMFORTIS 270 mg kauwtabl honden, katten; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					tabl katten, 1 pill of COMFORTIS 270 mg kauwtabl honden, katten and cutaneous contact with FRONTLINE COMBO spot-on katten. The delay between the incident and the phone call was 1 day.
28-Oct-2019	UAE; 19BE000146; -; Belgium	**Species:** Canine **Breed:** - **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** PO-Oral **Was the product used ok?:** No (Route not indicated / recommended)	17-Aug-2019*	17-Aug-2019	N/A	D-D	Poison Centre: call from an animal owner on 17/08/2019 concerning a dog showing apathy and malaise after ingestion of FRONTLINE COMBO spot-on honden S.
30-Oct-2019	UAE; 19BE000148; -; Belgium	**Species:** Canine **Breed:** - **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 50 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** PO-Oral **Was the product used ok?:** No (Route not indicated / recommended)	01-Aug-2019	02-Aug-2019	N/A	D-C	Poison centre: call from an animal owner on 2/08/2019 concerning a dog (50 kg) showing ataxia and hypersalivation after oral contact with FRONTLINE COMBO spot-on honden XL. The delay between the incident and the phone call was 1 day.
26-Nov-2019	UAE; 19BE000158; -; Belgium	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** - **Was the**	20-Nov-2019*	21-Nov-2019*	N/A	D-D	As reported by the attending pharmacist on 26NOC19, two dogs of the same household (ID name of animals, ages, weights, breeds, reproductive status unknown) were treated with Frontline Comboline (batch, expiry date, route, location, dose administered all unknown) for a supposed pre-existing flea problem. The product was administered by the pet owner to the two dogs on an unknown recent date. An unknown time after product administration the dog owner complained to the pharmacist that the product was not efficacious and that both dogs showed scratching lesions due to the flea infestation. No further analysis/tests were performed. The

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Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					current status of both dogs is unknown.
01-Oct-2019	UAE; 19BR004401; PR; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 18.00 Month(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Sep-2019	16-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Shih Tzu of 18 months old and 5 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 15 days ago (16 Sep 2019), for flea/tick control. The pet is still scratching herself. No ectoparasites were seen. Environment treated with Butox®. FL has been applied every 4 months since date not specified. No further information is expected.
01-Oct-2019	UAE; 19BR004408; BA; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** - **Age:** 3.00 Month(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Aug-2019	19-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a male shih tzu (Mayck, 3 months old, 3kg) received FRONTLINE SPRAY 250 mL (FL) (lot and exp date are unknown, topical, whole body) for the first time, applied by the reporter on 19 AUG 2019 because the dog itches too much, so it was recommended by the veterinarian because Mayck could have fleas. Lack of efficacy is suspected because the pet remains with some kind of parasite, however she cannot say if it´s flea or not as its a small black parasite. Environment not treated. No further information is available.
01-Oct-2019	UAE; 19BR004417; RS; Brazil	**Species:** Canine **Breed:** St. Bernard **Sex:** M **Sex qualifier:** Unknown **Age:** 3.50 Year(s) **Weight:** 37 kg	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** CAPSTAR; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Sep-2019	18-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Francisco, a male St Bernard, 3.5 years old weighting 37 Kg received FRONTLINE TOP SPOT XL, (FL) (exp date and batch unknown) applied by the animal owner on 17 SEP 2019 (2 days after giving bath, btw the shoulder blades directly on the skin according to the label) for flea and tick prevention, he also used Capstar on unknown date (18 Sep 2019*). Francisco does not have outdoor access and is bathed twice a month. According to the customer, Francisco have parasite-induced dermatitis and he is with fleas after the treatment so lack of efficacy is suspected . There is a dog that was treated with FL with no issue living in this house. Environment treated with K-Othrine®. No further information is available.
02-Oct-2019	UAE; 19BR004467; SP; Brazil	**Species:** Feline **Breed:** Feline various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Aug-2019*	15-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Guida, a female crossbred cat of 8 years old and 4 kg received 1 dose of FRONTLINE PLUS CATS (FL) (lot, exp date, topical, btw the shoulder blades), administered by the reporter on date not specified (21 Aug 2019*) for flea prevention. Lack of efficacy is suspected because the cat got fleas after treatment, so another application of FL was made on 21 Sep 2019 and the cat remains with fleas. FL was used in the past with no issue (dose frequency - monthly, date of first administration was not provided). The environment has not been treated. No further information is available.

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ED_005739D_00014391-00017

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
02-Oct-2019	UAE; 19BR004470; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 4.1 - 13.4 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	11-Aug-2019	11-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 dogs (Moly, a female Border Collie of 9 years old and 13.4 kg; Geyse, a female small crossbreed of 6 years old and 4.1 kg), received FRONTLINE SPRAY 250 mL (FL) (001/18A, unknown exp date, topical, whole body), applied by the reporter on 11 Aug 2019, 30 Aug 2019 and 2 Oct 2019, for flea treatment. Lack of efficacy is suspected because the animals still have fleas . FL was used in the past, every 6 months, with no issue (since date not provided). The environment has been treated with Butox® and K-Othrine®. No further information is expected.
01-Oct-2019	UAE; 19BR004473; RJ; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Sep-2018*	Sep-2018*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, three dogs were treated with FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Sep 2019 - chosen at random). The product was not effective. The owner also complained about the lack of efficacy of NEXGARD (see cases 19BR004412, 19BR004413 and 19BR004414). No further information is expected.
02-Oct-2019	UAE; 19BR004476; RJ; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 12 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	Sep-2019*	Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Scooby, a male crossbred dog of 2 years old and 12 kg, received one pipette of FRONTLINE PLUS DOGS M (FL) (lot and exp date are unknown, topical, belly and from base of skull to low back – off-label use) for the first time, administered by the reporter on approx. Sep 2019 for flea treatment. Lack of efficacy is suspected because fleas continued to be found after product administration. It is unknown if Scooby is currently presenting fleas. Scooby is bathed once a week. There is an untreated dog living in the same household. Environment treated with Butox®. No further information is available.
01-Oct-2019	UAE; 19BR004477; -; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown	29-Sep-2019	29-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a Yorkshire Terrier of unknown signalment, received FRONTLINE (FL) (unsubstantiated; lot, exp date, route and location are unknown) administered by the reporter on 29 Sep 2019 for flea treatment. Lack of efficacy is suspected because fleas continue to be found on the dog. This is the extent of the information available for now.

N/A signifies the information for this field is either not available or not applicable

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ED_005739D_00014391-00018

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					
07-Oct-2019	UAE; 19BR004496; SP; Brazil	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.50 Year(s) **Weight:** 6.8 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Sep-2019	22-Sep-2019	0 Day(s)	D-D	As reported by the pet owner, one female pet (species unknown) received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and application site unknown), administered by the reporter on around 15 days ago (19 Sep 2019*) for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. This is the extent of the information available. UPDATE 7 OCT 2019 - Belinha, a female Poodle x Maltese of 5.5 years old and 6.8 kg, was treated with one vial of FL SPOT-ON DOGS S (FL) (topical, btw the shoulder blades), applied by the reporter on 22 Sep 2019. The pet remains with fleas. In addition, the pet is scratching herself due to fleas. Environment not treated. The pet has outdoor access. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). No further information is expected.
03-Oct-2019	UAE; 19BR004503; RJ; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Sep-2018*	01-Sep-2018*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one dog of unknown signalment was treated with FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Sep 2018 - chosen at random). The product was not effective (details were not provided). The owner also complained about the lack of efficacy of NEXGARD (see cases 19BR004500, 19BR004501 and 19BR004502). No further information is expected.
03-Oct-2019	UAE; 19BR004523; SP; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 9.8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Sep-2019	22-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nero, a male small crossbred dog of 4 years old and 9.8 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (022/18A, unknown exp date, topical, btw the shoulder blades), applied by the reporter on 22 Sep 2019, for flea/tick treatment. The pet remains with ectoparasites. Environment not treated. FL has been applied only when the owner sees ectoparasites (dose frequency is unknown and first application was not provided). No further information is expected.
04-Oct-2019	UAE; 19BR004527; RJ; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 5 - 6 kg	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment /	01-Oct-2019	01-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 female mixed breed cats of 4 to 12 years old and around 5 to 6 kg, were treated, for the first time, with one vial of FRONTLINE PLUS CATS (FL) (007/18A, unknown exp date, topical, btw the shoulder blades to the tail), applied by the reporter on 1 Oct 2019, for flea treatment. The animals remain with fleas. Environment not treated. No further information is expected.

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ED_005739D_00014391-00019

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						vaccination program not respected)					
03-Oct-2019	UAE; 19BR004528; TO; Brazil	**Species:** Canine **Breed:** Shepherd Dog (Others) **Sex:** X **Sex qualifier:** Unknown **Age:** 1.30 Year(s) **Weight:** 26 - 34 kg	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Sep-2019	30-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 Shepherd Dogs (Hera, female, 2.5 years old, 28 kg; Athena, female, 1.3 years old, 26 kg; Heros, male, 1.3 years old, 34 kg) received one pipette of FRONTLINE L (FL) (unsubstantiated; lot and exp date are unknown, topical, btw the shoulder blades) each, administered by the reporter on 30 Sep 2019 for tick treatment. Lack of efficacy is suspected because ticks are still being found on the dogs. FL has been given every 30-45 days (1st adm date not provided - Jan 2019*) with no issue. There is another dog living in the same household that has been simultaneously treated with Nexgard® (SLOE case reported on 19BR004530). The pet owner mentioned that there are some people complaining about FL, however, details and valid patient info were not provided. Environment partially treated with K-Othrine®. No further information is available.
04-Oct-2019	UAE; 19BR004531; RJ; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Month(s) **Weight:** 3 - 3.3 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	03-Sep-2019	03-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two female Yorkies (Jolie, 3 years old and 3 kg; Melissa, 14 months old and 3.3 kg) were treated, for the first time, with FRONTLINE SPRAY 100 mL (FL) (002/18B, unknown exp date, topical, back - low dose), applied by the reporter on 3 Sep 2019, for flea/tick treatment. The animals remained with ectoparasites, so new applications of FL (whole body) were made on 17 Sep 2019 and 26 Sep 2019. The dogs remain with fleas and ticks. Environment treated with an unknown product. No further information is expected.
02-Oct-2019	UAE; 19BR004535; -; Brazil	**Species:** Canine **Breed:** Lhasa Apso **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	18-Sep-2019	02-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a Lhasa Apso of unknown signalment received FRONTLINE (FL) (unsubstantiated; lot, exp date, route and location are unknown) administered by the reporter on 18 Sep 2019 for ectoparasite control. Lack of efficacy is suspected because one live tick was found on the dog. Environmental factors and other details are not known. No further information is available.
04-Oct-2019	UAE; 19BR004538; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 14 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	13-Sep-2019	16-Sep-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Amora, a female medium crossbred dog of 2 years old and 14 kg, received one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 13 Sep 2019, for tick treatment. Ticks have died, however, they returned 3 days after product application. FL has been used every 5 months since date not specified. Environment treated with Butox®. No further information is expected.

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ED_005739D_00014391-00020

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** Yes					
03-Oct-2019	UAE; 19BR004539; RJ; Brazil	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 4 kg	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Sep-2019*	12-Sep-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Duquesa, a female Domestic Shorthair (crossbred) cat of 3 years old and 4 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on approx. 5 Sep 2019 for flea treatment. Lack of efficacy is suspected because Duquesa continues to scratch herself and fleas returned to be found since approx. 12 Sep 2019. The pet owner attributes the itching to the flea infestation. It is unknown if FL has been administered in the past. There are 2 other cats of the same household that have been simultaneously treated with FL with no issue and 4 dogs also from the same household that have been treated with Bravecto®. Environment treated with unknown product. No further information is available.
07-Oct-2019	UAE; 19BR004576; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Sep-2019	23-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Fred, a male mixed breed cat of 6 months old and 3 kg, was treated, for the first time, with FRONTLINE SPRAY 100 mL (005/18A, unknown exp date, topical whole body), applied by the reporter on 23 Sep 2019, for flea treatment. The animal remains with fleas. Environment not treated. Similar case with other cat that was treated with FL with the same issue reported on 19BR004577. No further information is expected.
07-Oct-2019	UAE; 19BR004577; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 18.00 Month(s) **Weight:** 5.3 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Sep-2019	23-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Deluka, a male mixed breed cat of 18 months old and 5.3 kg, was treated with FRONTLINE SPRAY 100 mL (005/18A, unknown exp date, topical whole body), applied by the reporter on 23 Sep 2019, for flea treatment. The animal remains with fleas. Environment not treated. FL has been applied every 6 months with no issue since date not specified. Similar case with other cat that was treated with FL with the same issue reported on 19BR004576. No further information is expected.
07-Oct-2019	UAE; 19BR004595; SP; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Sep-2019*	12-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Milu, a female Shih Tzu of 6 years old and 6 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 12 Sep 2019, for flea treatment. The pet remains with fleas. Environment not treated. FL has been applied every 3 months with no issue since date not specified. No further information is expected.
07-Oct-2019	UAE;	**Species:** Canine	1	1	0	**Product used:**	23-Jun-2019*	07-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner,

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ED_005739D_00014391-00021

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19BR004598; RS; Brazil	**Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 15 kg				FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					Marry, a female medium crossbred dog of 15 years old and 15 kg, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 23 Jun 2019 for flea prevention. The pet got fleas after treatment, so new applications of FL (013/18A) were made around 7 Aug 2019 and around 28 Sep 2019 and the pet remains with fleas. Environment not treated. FL has been applied every 45 days since date not specified. No further information is expected.
07-Oct-2019	UAE; 19BR004602; -; Brazil	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** X **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 20 - 25 kg	3	3	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Sep-2019	02-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 German Shepherd Dogs of mixed sex, 7 to 12 years old and 20 to 25 kg, were treated, for the first time, with FRONTLINE SPRAY 250 mL (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on 2 Sep 2019, for flea treatment. The animals remain with fleas. Environment treated with Butox®. Similar case with a cat that lives in the same house and received FL with the same issue reported on 19BR004603. No further information is expected.
07-Oct-2019	UAE; 19BR004603; -; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Sep-2019	02-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Tieta, a female mixed breed cat of 6 years old and 3 kg, was treated, for the first time, with FRONTLINE SPRAY 100 mL (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on 2 Sep 2019, for flea treatment. The animal remains with fleas. Environment treated with Butox®. Similar case with dogs that live in the same house and received FL with the same issue reported on 19BR004602. No further information is expected.
08-Oct-2019	UAE; 19BR004607; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 35.00 Day(s) **Weight:** 1 - 9 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	04-Sep-2019	04-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two dogs (Charlie, a male Pug of 35 days old and 1 kg; Beni, a male Dachshund of 10 years old and 9 kg), were treated with FRONTLINE SPRAY 100 mL (FL) (002/19A, unknown exp date, topical, parts of the body - low dose), applied by the reporter on 4 Sep 2019, 15 Sep 2019 (estimated date) and 6 Oct 2019, for flea treatment. The animals remain with fleas. Environment treated with deltamethrin. Similar case with a cat that received FL with the same issue reported on 19BR004608. No further information is expected.
08-Oct-2019	UAE; 19BR004608; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products	04-Sep-2019	04-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Sheik, a male mixed breed cat of 6 months old and around 700 g, was treated with FRONTLINE SPRAY 100 mL (FL) (002/19A, unknown exp date, topical, parts of the body - low dose), applied by the reporter on 4 Sep 2019, 15 Sep 2019 (estimated date) and 6 Oct 2019, for flea treatment. The animal remains with fleas.

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ED_005739D_00014391-00022

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 6.00 Month(s) **Weight:** 700 gms				**Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					Environment treated with deltamethrin. Similar case with dogs that received FL with the same issue reported on 19BR004607. No further information is expected.
08-Oct-2019	UAE; 19BR004609; SP; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Sep-2019	25-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Theo, a male Yorkshire of 11 years old and 6 kg, was treated with FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 25 Sep 2019, for flea treatment. The animal remains with fleas. Environment treated with deltamethrin. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). Similar case with other dog that received FL with the same issue reported on 19BR004610. No further information is expected.
08-Oct-2019	UAE; 19BR004610; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 11 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Sep-2019	25-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Brita, a female medium crossbred dog of 6 years old and 11 kg, was treated with FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 25 Sep 2019, for flea treatment. The animal remains with fleas. Environment treated with deltamethrin. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). Similar case with other dog that received FL with the same issue reported on 19BR004609. No further information is expected.
07-Oct-2019	UAE; 19BR004626; RN; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 12 - 19 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	01-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, two dogs of unknown signalment were treated with FRONTLINE (unsubstantiated) (FL) (lot and exp date, route and location are unknown), administered by the reporter on date not specified (1 Oct 2019 - chosen at random) for flea treatment. The animals remain with fleas. This is the extent of the information available. UPDATE 23 OCT 2019 - The owner was contacted and reported that her two female medium crossbred dogs (Venus, 2 years old and 12 kg; Baleia, 3 years old and 19 kg) were treated, for the first time, with one vial of FL PLUS DOG M (topical, btw the shoulder blades), applied, on each one, by the reporter on 1 Oct 2019, for flea treatment. The animals remained with fleas. So, the reporter administered an unknown tablet to her dogs and they are currently free of fleas. Environment not treated. No further information is expected.
09-Oct-2019	UAE; 19BR004639; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:**	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other	2018*	2018*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, two female dogs (Maria Vitória, Dachshund, 13 years old and around 7.8 kg; Luiza, small crossbred dog of 8.5 kg and unknown age) were treated with FRONTLINE SPRAY 100 mL (lot and exp date are unknown, topical, whole body), applied by the reporter last year

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ED_005739D_00014391-00023

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** 13.00 Year(s) **Weight:** 7.8 - 8.5 kg				products **Route:** unknown **Was the product used ok?:** Unknown to Company					(2018*). After product application, the animals presented itching. Both of them were taken to the vet, who suspected of FL. SLOE case reported on 19BR004640. No further information is available.
09-Oct-2019	UAE; 19BR004640; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 7.8 - 8.5 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Sep-2019	19-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two female dogs (Maria Vitória, Dachshund, 13 years old and around 7.8 kg; Luiza, small crossbred dog of 8.5 kg and unknown age) were treated with FRONTLINE SPRAY 100 mL (002/18A, unknown exp date, topical, whole body), applied by the reporter on 19 Sep 2019, for flea treatment. They started presenting fleas 1 week prior to FL. Lack of efficacy is suspected because the dogs remain with fleas. Environment treated with Butox®. FL was applied in the past (dose frequency is unknown and first application was not provided). SAE case reported on 19BR004639. No further information is expected.
08-Oct-2019	UAE; 19BR004642; RJ; Brazil	**Species:** Canine **Breed:** Shar Pei **Sex:** F **Sex qualifier:** Unknown **Age:** 19.00 Month(s) **Weight:** 15.4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	01-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Raika, a female Shar Pei of 19 months old and 15.4 kg, was treated, for the first time, with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 1 Oct 2019, for flea treatment. The number of fleas has decreased, however, the pet remains with ectoparasites. Environment treated with an unknown product. No further information is expected.
07-Oct-2019	UAE; 19BR004644; SP; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	30-Sep-2019*	30-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lili, a female Shih Tzu of 5 years old and 6 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (022/18B, exp date is unknown, topical, btw the shoulder blades) administered by the reporter on approx. 4 Oct 2019* for tick treatment. Lack of efficacy is suspected because ticks are still being found on the dog. Same issue occurred after the previous FL (same presentation, batch, route and location) application which was performed on approx. 30 Sep 2019*. Before these last 2 applications FL has been administered in the past with issue (dose frequency and 1st adm date not provided). Once a week Lili use to be bathed. Environment not treated. No further information is available.
08-Oct-2019	UAE; 19BR004656; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** FIPRONIL SPOT ON CAT; **Route:** unknown	15-Sep-2019*	15-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 2 cats of unknown signalment received FRONTLINE SPRAY (FL SPRAY) (lot, exp date, route and location are unknown) administered by the reporter on date not informed (15 Sep 2019*). Some fleas were found dead after product administration, however, live fleas continued to be seen. So, on approx. 24 Sep 2019 FRONTLINE (pipette presentation – unsubstantiated; lot, exp date, route and location are unknown)

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* indicates Approximate date or weight.

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ED_005739D_00014391-00024

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					was administered and it was not effective either. The cats remain with fleas. This is the extent of the information available for now.
10-Oct-2019	UAE; 19BR004663; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Sep-2019*	25-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female mixed breed cat of 12 years old and around 4 kg, was treated, for the first time, with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 25 Sep 2019, for flea treatment. The pet remains with fleas and she is scratching herself due to fleas. Environment treated with Butox®. No further information is expected.
09-Oct-2019	UAE; 19BR004665; SP; Brazil	**Species:** Canine **Breed:** Dachshund **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 10 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	26-Sep-2019	26-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, New, a male Dachshund of 6 years old and 10 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, back; off-label use) administered by the reporter on 26 Sep 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. FL has been administered every 3 months (1st adm date not provided) with no issue. Environment treated with an unknown product. Similar case with a dog that received FL with the same issue reported on 19BR004666. No further information is available.
09-Oct-2019	UAE; 19BR004666; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 1.30 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	26-Sep-2019	26-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Dory, a female crossbred cat of 1.3 years old and 5 kg, received one pipette of FRONTLINE SPOT-ON CAT (FL) (lot and exp date are unknown, topical, back) administered by the reporter on 26 Sep 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. FL has been administered every 3 months (1st adm date not provided) with no issue. Environment treated with an unknown product. Similar case with a dog that received FL with the same issue reported on 19BR004665. No further information is available.
11-Oct-2019	UAE; 19BR004667; -; Brazil	**Species:** Canine **Breed:** Pomeranian **Sex:** U **Sex qualifier:** Unknown **Age:** 5.00 Month(s) **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL SPRAY **Other products used:** Unknown vaccine; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination	07-Oct-2019	07-Oct-2019*	0 Day(s)	D-A	Suspected Adverse Event: As reported by the veterinarian via BI employee, a Pomeranian of 5 months received FRONTLINE SPRAY (FL) (lot and exp date unknown, topical, withers – incorrect administration/low dose) for the first time, administered on 7 Oct 2019 for tick treatment. The dog was vaccinated with unknown vaccine 5 days prior to FL. A while after product administration the animal presented unspecified reaction. He was hospitalized and died 5 days after product administration (12 Oct 2019). The veterinarian that attended the dog believes that it was intoxicated by FL. Necropsy was performed and showed gastroenteritis. It is unknown if the necropsy showed other alterations. This is the extent of the information available.

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ED_005739D_00014391-00025

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						program not respected)					
09-Oct-2019	UAE; 19BR004670; MG; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 5 - 7 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	25-Sep-2019	25-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two dogs (Pepeu, male Lhasa Apso of 3 years old and around 5 kg; Pepita, a female Poodle of 3 years old and around 7 kg) were treated, for the first time, with an unknown dose of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades to the tail), applied by the reporter on 25 Sep 2019, for flea/tick treatment. The animals remain with ectoparasites. Environment treated with Butox®. No further information is expected.
10-Oct-2019	UAE; 19BR004678; RJ; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 13 kg	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL SPRAY; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Jul-2019*	23-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female dog of unknown signalment was treated with FRONTLINE PLUS (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on Jul 2019, Aug 2019 and Sep 2019, for flea treatment. The pet remains with fleas. Environment treated with Butox®. This is the extent of the information available. UPDATE 15 OCT 2019 - Carolina, a female medium crossbred dog of 8 months old and 13 kg, was treated with one vial of FL (topical, btw the shoulder blades), applied by ther reporter around 23 Jul 2019 (first time), around 23 Aug 2019 and on 23 Sep 2019, for flea treatment. The pet remains with fleas. Environment treated with Butox®. The owner also complained that FL SPRAY was applied 2 times (frequency is unknown) around 2 months ago (Aug 2019*) and the flea infestation decreased but continued. There is one more dog in this household and one cat - both were treated with FL SPRAY and they have no issue. No further information is expected.
11-Oct-2019	UAE; 19BR004679; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 16 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	01-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Meg, a female medium crossbred dog of 1 years old and 16 kg, was treated, for the first time, with one vial of FRONTLINE SPOT-ON DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 1 Oct 2019, for flea treatment. The pet remains with fleas. Environment not treated. No further information is expected.
10-Oct-2019	UAE; 19BR004698; RJ; Brazil	**Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 7 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	Aug-2019*	Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Lhasa Apso of 11 years old and 7 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (022/18A, exp date is unknown, topical, btw the shoulder blades and back) administered by the reporter on date not informed (Aug 2019*) for flea/tick control. Lack of efficacy is suspected because the pet got fleas after treatment, so another application of FL was made on approx. 4 Oct 2019 and the dog remains with fleas. FL was administered in

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ED_005739D_00014391-00026

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					the past (approx. every 2-3 months, 1st adm date not provided - 2017*) with no issue. Mel is bathed weekly. Environment not treated. Similar case reported on 19BR004699. No further information is available.
10-Oct-2019	UAE; 19BR004699; RJ; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 10 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	Aug-2019*	Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Sol, a female crossbred dog of 8 years old and approx. 10 kg, received one pipette of FRONTLINE PLUS DOGS M (FL) (020/18A, exp date is unknown, topical, btw the shoulder blades and back) administered by the reporter on date not informed (Aug 2019*) for flea/tick control. Lack of efficacy is suspected because the pet got fleas after treatment, so another application of FL was made on approx. 4 Oct 2019 and the dog remains with fleas. FL was administered in the past (approx. every 2-3 months, 1st adm date not provided - 2017*) with no issue. Sol is bathed weekly. Environment not treated. Similar case reported on 19BR004698. No further information is available.
10-Oct-2019	UAE; 19BR004700; SP; Brazil	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 16.00 Year(s) **Weight:** 23 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a dog of unknown signalment received FRONTLINE (FL) (unsubstantiated; lot, exp date, route and location are unknown) administered by the reporter on date not informed (Sep 2019*). According to the reporter, the product was administered according to the pet's weight. Lack of efficacy is suspected because the dog remains with fleas. FL has been administered 'since always' with no issue (dose frequency and 1st adm date not provided). This is the extent of the information available for now. UPDATE 21 OCT 2019 - The owner was contacted and reported that Rex, a male large crossbred dog of 16 years old and 23 kg, was treated with one vial of FL SPOT-ON DOGS L (FL) (topical, btw the shoulder blades), applied by the reporter around 20 days ago (1 Oct 2019 - estimated date). However, the pet remains with fleas. In addition, Rex has flea allergy dermatis. Environment treated with an unknown product. FL has been applied every 6 months since date not specified. No further information is available.
11-Oct-2019	UAE; 19BR004715; PR; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 5 - 8 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	19-Jun-2019*	19-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 dogs (Julie, female, Lhasa Apso, 17 years old, 5 kg; Azeitona, male, Shih Tzu, 4 years old, 8 kg) received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date unknown, topical, btw the shoulder blades) each, administered by the reporter on date not specified (19 Jun 2019*) for flea/tick control. Lack of efficacy is suspected because approximately 2 months after treatment, fleas started to be visualized on the dogs. Another application of FL was made on 19 Sep 2019 (022/18A, exp date is unknown) and the dogs remain with fleas. Due to this, both received Nexgard® (28.3 mg) on today's date (11 Oct 2019) for flea treatment but there is still no information regarding if lack of

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ED_005739D_00014391-00027

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					efficacy is also suspected for this product. FL has been administered every 3 months (1st adm date not provided – 2018*) and same issue occurred other times in the past (see case 19BR004716). The dogs are bathed weekly. Environment not treated. No further information is available.
11-Oct-2019	UAE; 19BR004716; PR; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2018*	2018*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 dogs (Julie, female, Lhasa Apso, unknown age and weight; Azeitona, male, Shih Tzu, unknown age and weight) received FRONTLINE (FL) (unsubstantiated; lot, exp date, route and location are unknown) administered by the reporter on dates not informed (2018* - estimated) for flea treatment. Lack of efficacy is suspected because the dogs continued to present with fleas an unknown number of times after product administration. Related case reported on 19BR004715. This is the extent of the information available for now.
12-Oct-2019	UAE; 19BR004717; RS; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 11 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Sep-2019	15-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pituca, a female medium crossbred dog of 10 years old and around 11 kg, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 15 Sep 2019, for flea treatment. According to the owner, after product application, the number of fleas has increased. Environment treated with Colosso. The pet has outdoor access. FL was applied in the past with no issue (dose frequency: every 15 days during summer and spring; every 2 months during winter). No further information is expected.
11-Oct-2019	UAE; 19BR004720; SP; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 12 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019*	08-Oct-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Floquinho, a male Shih Tzu (other signalment is unknown) was treated with FRONTLINE SPOT-ON DOGS M (FL) (lot, exp date, route and location are unknown), applied by the reporter around 1 Oct 2019, for flea treatment. One week post FL application, the owner noticed some fleas on her dog. Similar case with other dog that received FL with the same issue reported on 19BR004721. No further information is available. UPDATE 21 OCT 2019 - Floquinho, a male Shih Tzu of 8 years old and 12 kg, was treated with one vial of FL (topical, btw the shoulder blades), applied by the reporter around 1 Oct 2019*, for flea treament. Fleas were seen for 1 week and then, no ectoparasite has been visualized. The pet has outdoor access. Environment not treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). No further information is available.
11-Oct-2019	UAE; 19BR004721; SP; Brazil	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Unknown **Age:** 15.00 Month(s)	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous	01-Oct-2019*	08-Oct-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Buddy, a male Golden (other signalment is unknown) was treated with FRONTLINE SPOT-ON DOG L (FL) (lot, exp date, route and location are unknown), applied by the reporter around 1 Oct 2019, for flea treatment. One week post FL application, the owner noticed some fleas on her dog. Similar case with other dog that received FL with the same issue reported on 19BR004720. No further information is available. UPDATE 21 OCT

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ED_005739D_00014391-00028

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 35 kg				**Was the product used ok?:** Yes					2019 - Buddy, a male Golden Retriever of 15 months old and 35 kg, was treated with one vial of FL (topical, btw the shoulder blades), applied by the reporter around 1 Oct 2019, for flea treament. Fleas were seen for 1 week and then, no ectoparasite has been visualized. The pet has daily outdoor access. Environment not treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). No further information is available.
13-Oct-2019	UAE; 19BR004722; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Month(s) **Weight:** 1.7 - 7 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, her two female cats were treated with FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Oct 2019 - chosen at random), for flea treatment. The animals remain with fleas. Environment treated with an unknown product. This is the extent of the information available. UPDATE 21 OCT 2019 - The reporter was contacted and informed that her two female mixed breed cats (Mia, unknown age and 7 kg; Isa, 5 months old and 1.7 kg) were treated, for the first time, with one vial of FL CATS (unknown if it was SPOT-ON or PLUS) (topical, btw the shoulder blades), applied to each one by the reporter on date not specified (1 Oct 2019*). The animals still have fleas. Environment treated with Butox®. No further information is expected.
15-Oct-2019	UAE; 19BR004729; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Week(s) **Weight:** 750 gms	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	09-Oct-2019	09-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Niko, a male crossbred cat of 4 weeks old and 750 g, was treated, for the first time, with FRONTLINE SPRAY 100 mL (lot and exp date are unknown, topical, unknown location), applied by the reporter on 9 Oct 2019, for flea treatment. The owner continued to see fleas on her pet. So, she administered Capstar® and now fleas have died. Environment treated with deltamethrin. No further information is expected.
12-Oct-2019	UAE; 19BR004741; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Oct-2019	10-Oct-2019*	1 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Pretinho, a male mixed breed cat of 10 years old and 4 kg, was treated with one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical btw the shoulder blades), applied by the reporter around 9 Oct 2019, for flea treatment. One day post product application, the pet presented with intense vomiting and the symtom stopped 3 days later. In addition, the pet also experienced application site hair loss and application site lesion. Hipoglós® was applied by the owner. The pet has recovered. No vet care was provided. The pet has outdoor access. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). No further information is available.
15-Oct-2019	UAE; 19BR004752; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the pet owner, an unknown number of cats of unknown signalment, received FRONTLINE SPRAY (Unsubstantiated; lot and exp date is unknown, topical, btw the shoulder blades - off label use) (FL) applied by the reporter on an unknown date (1 Oct 2019 - chosen at random) for unknown reason. According to the pet owner the product was not effective. Environmental factors are not known. This is the extent of the information available.

N/A signifies the information for this field is either not available or not applicable

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* indicates Approximate date or weight.

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ED_005739D_00014391-00029

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: No (Treatment / vaccination program not respected)					
15-Oct-2019	UAE; 19BR004763; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 1.30 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Sep-2019	18-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nick, a male crossbreed cat of 1.3 years old and 5 kg, received 1 dose of FRONTLINE PLUS CATS (batch and exp. date unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 18 Sep 2019 for flea treatment. The ectoparasites were seen for at least one year prior to FL administration . Lack of efficacy is suspected because the pet remains with fleas . There is another dog in the same household that has been treated with NEXGARD with no issue. Nick is bathed once a week. The environment has been treated with Butox®. No further information is available.
14-Oct-2019	UAE; 19BR004768; -; Brazil	**Species:** Canine **Breed:** Rottweiler **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the pet owner via e-mail, Atena, a female Rottweiler of 2 months old and unknown weight, received FRONTLINE SPRAY (lot and exp date is unknown, topical, whole body) (FL) applied by the reporter on an unknown date (1 Oct 2019*) for tick treatment. Lack of efficacy is suspected because ticks were found on Atena . Environmental factors are not known. This is the extent of the information available.
15-Oct-2019	UAE; 19BR004770; RJ; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 12 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019	01-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the pet owner, Ducke, a male crossbreed dog of 4 years old and 12 kg, received one pipette of FRONTLINE PLUS DOGS M (lot and exp date is unknown, topical, back) (FL) for the first time, applied by the reporter on 1 Oct 2019 for flea treatment. Lack of efficacy is suspected because Ducke remains with fleas. In addition, the pet has flea allergy dermatitis. Environment treated with Butox®. No further information is available.
04-Oct-2019	UAE; 19BR004772; PR; Brazil	**Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 7 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	04-Sep-2019*	04-Sep-2019*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, July, a female Lhasa Apso of 9 years old and 7 kg, received FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, base of skull and btw the shoulder blades) on approx. 4 Sep 2019* for flea/tick control. Right after the application July experienced agitation and itching. According to the reporter, she had the impression that 'the product was burning on the dog's skin'(discomfort NOS). July recovered spontaneously shortly after. SLOE case related to the same patient was reported on 19BR004324. This is the extent of the information available.

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ED_005739D_00014391-00030

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					
15-Oct-2019	UAE; 19BR004779; RJ; Brazil	**Species:** Feline **Breed:** Turkish Angora **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Sep-2019*	15-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Turkish Angora of approximately 6 years old and around 4 kg, was treated with FRONTLINE SPRAY 100 mL (FL) (lot and exp date are unknown, topical, whole body) for the first time, applied by the reporter last month (15 Sep 2019 - estimated date), for flea treatment. The owner still sees fleas on her pet. Environment not treated. SAE case reported on 19BR004780. No further information is expected.
15-Oct-2019	UAE; 19BR004780; RJ; Brazil	**Species:** Feline **Breed:** Turkish Angora **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Sep-2019	15-Sep-2019*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Mel, a female Angora of approximately 6 years old and around 4 kg, was treated with FRONTLINE SPRAY 100 mL (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter last month (15 Sep 2019 - estimated date), for flea treatment. Some hours post FL application, the pet presented one episode of vomiting and hypersalivation. She recovered on the same day. SLOE case reported on 19BR004779. No further information is expected.
08-Oct-2019	UAE; 19BR004785; MG; Brazil	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 11 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	08-Sep-2019*	06-Oct-2019	4 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Sky, a female Labrador Retriever of 6 months old and 11 kg, received one pipette of FRONTLINE (FL) (unsubstantiated; lot and exp date are unknown; topical, btw the shoulder blades) administered by the reporter on approx. 8 Sep 2019 for tick treatment. Lack of efficacy is suspected because on 6 Oct 2019 one live tick was found on the dog. Prior to 6 Oct 2019 the environment had not been treated (K-Othrine® was administered only on the date of tick discovery). Similar issue (same patient) reported on 19BR004365. No further information is available.
11-Oct-2019	UAE; 19BR004787; SP; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 12 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	20-Aug-2019	20-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Max, a male neutered dog of 10 years old and 12 kg, was treated with one vial of FRONTLINE SPOT ON DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 20 Aug 2019, for flea treatment. The owner continued to see fleas on her dog. So, she applied one more vial of FL on 10 Sep 2019. However, her pet still has fleas. Environment treated with an unknown product. FL has been applied every 6 months since date not specified. Similar cases with other animals that received FL with the same issue reported on 19BR004788 and 19BR004789. No further information is expected.
11-Oct-2019	UAE; 19BR004788;	**Species:** Canine **Breed:** Canine	1	1	0	**Product used:** FIPRONIL SPOT	20-Aug-2019	20-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Fofolete, a female dog of 17 years old and 9 kg, was treated with

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ED_005739D_00014391-00031

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	SP; Brazil	(unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 17.00 Year(s) **Weight:** 9 kg				ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					one vial of FRONTLINE SPOT ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 20 Aug 2019, for flea treatment. The owner continued to see fleas on her dog. So, she applied one more vial of FL on 10 Sep 2019. However, her pet still has fleas. Environment treated with an unknown product. FL has been aplied every 6 months since date not specified. Similar cases with other animals that received FL with the same issue reported on 19BR004787 and 19BR004789. No further information is expected.
11-Oct-2019	UAE; 19BR004789; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** U **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 4.000 - 5.5 kg	11	11	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	20-Aug-2019	20-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 11 mixed breed cats of 8 months to 14 years old and 4 kg to 5.5 kg, were treated with one vial of FRONTLINE SPOT ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied to each one by the reporter on 20 Aug 2019, for flea treatment. The owner continued to see fleas on her cats. So, she applied one more vial of FL on 10 Sep 2019. However, her pets still have fleas. Environment treated with an unknown product. FL has been aplied every 6 months since date not specified. Similar cases with dogs that received FL with the same issue reported on 19BR004787 and 19BR004788. No further information is expected.
17-Oct-2019	UAE; 19BR004818; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 18.00 Month(s) **Weight:** 3.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Aug-2019	28-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Marcha, a male mixed breed cat of 18 months old and 3.5 kg, was treated, for the first time, with one dose of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 28 Aug 2019, for flea treatment. However, the pet remains with fleas. Environment treated with Butox®. No further information is expected.
16-Oct-2019	UAE; 19BR004820; SP; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	2017*	2017*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Frederico, a male crossbred dog of approx. 5 years old and unknown weight, received FRONTLINE (FL) (unsubstantiated pipette; lot and exp date are unknown; topical, btw the shoulder blades) on approx. 2017* (estimated) for unknown reason. Intense itching and skin dyschromia (according to the reporter, his skin became 'darker') at the application site were experienced by Frederico after product administration (exact chronology to onset was not provided). Both signs improved an unknown time later. It is unknown if at the time the dog was taken to the veterinarian. Related cases reported on 19BR004714, 19BR004819 and 19BR004821. This is the extent of the information available.
16-Oct-2019	UAE; 19BR004821;	**Species:** Canine **Breed:** Canine	3	3	0	**Product used:** FIPRONIL SPOT	2017*	2017*	0 Day(s)	D-D	Suspected Adverse Event: As reported by a person not related to the patients of this case, an unknown number dogs of unknown

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ED_005739D_00014391-00032

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	SP; Brazil	(unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					signalment received FRONTLINE (FL) (unsubstantiated; lot, exp date, route and location are unknown) administered by unknown person on dates not informed (2017* - estimated). An unknown time after FL use, the animals experienced allergy (location and allergy features were not provided). Related cases reported on 19BR004714, 19BR004819 to 19BR004821. This is the extent of the information available.
17-Oct-2019	UAE; 19BR004822; SP; Brazil	**Species:** Canine **Breed:** Bull Terrier **Sex:** X **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 25 - 38 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Oct-2019	15-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two Bull Terriers (Sutão, male, 11 years old and 38 kg; Sofia, female, 14 years old and 25 kg) were treated with one vial of FRONTLINE PLUS DOG L (032/18A, unknown exp date, topical, btw the shoulder blades), applied to each one by the reporter on 15 Oct 2019, for flea treatment. However, the animals remain with fleas after product application. Environment treated with Butox®. FL has been applied once a year with no issue since date not specified. No further information is expected.
18-Oct-2019	UAE; 19BR004823; SP; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 8.7 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2017	2017*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the veterinarian, Hulk, a male small crossbred dog of 5 years old and 8.7 kg, was treated with one vial of FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter 3 years ago (2017*), for unknown reason. After product application (exact time to onset is unknown), the pet presented an allergic reaction (details were not informed). He was treated and has recovered. The pet has history of allergy to deodorant/perfumes. No further information is expected.
17-Oct-2019	UAE; 19BR004830; SC; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	09-Oct-2019	17-Oct-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a female dog of unknown signalment was treated with FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on 11 Oct 2019, for flea treatment. On 17 Oct 2019, the owner noticed some fleas on her pet. In addition, her belly was presenting wounds due to flea bites. This is the extent of the information available. UPDATE 7 NOV 2019 - The owner was contacted and reported that Laila, a female Yorkshire of 7 months old and 6 kg, was treated, for the first time, with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, 'back' - unknown location), applied by the reporter on 9 Oct 2019, for flea control. However, fleas have been found on her pet. Environment not treated. No further information is expected.
18-Oct-2019	UAE; 19BR004841; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	18-Oct-2019	18-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pipoca, a female medium crossbred dog of 10 years old and around 16 kg, was treated, for the first time, with one vial of FRONTLINE PLUS DOG M (FL) (013/18A, unknown exp date, topical, btw the shoulder blades), applied by the reporter on 18 Oct 2019. Five minutes post product application, the dog presented

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ED_005739D_00014391-00033

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** 10.00 Year(s) **Weight:** 16 kg				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					with itching, agitation and he is rubbing himself on things. Pipoca is showing some improvement, but the symtoms are still ongoing. No vet care was provided. The owner used to apply FL SPOT-ON with no issue. No further information is available.
18-Oct-2019	UAE; 19BR004842; RS; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** PO-Oral **Was the product used ok?:** Unknown to Company	12-Oct-2019	18-Oct-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female dog (other signalment is unknown) was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 12 Oct 2019, for flea treatment. On 18 Oct 2019, the owner noticed that her pet still had fleas. It is unknown if FL has previously been applied. Environment not treated. No further information is expected.
18-Oct-2019	UAE; 19BR004844; MA; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 12 - 16 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** Triatox®; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	30-Sep-2019	30-Sep-2019	N/A	D-D	Suspected Lack of Efficacy: As reported by the pet owner, 2 dogs (Esmeralda, female crossbreed dog, 7 years old, 16 kg; Pretinha, female crossbreed dog, 2 years old, 12 kg), received FRONTLINE SPRAY 250 ML (003/18; exp date is unknown, topical, whole body) (FL) applied by the reporter on 30 Sep 2019 for flea treatment. According to the reporter, the product was not effective. On 7 Oct 2019 FL was applied again but the dogs remain with fleas. FL has been applied every 15 days (first administration date not provided) with no issue. Both dogs have been bathed with Triatox® every 15 days. There are 14 cats living in the same household that have not been treated. Environment not treated. No further information is available.
20-Oct-2019	UAE; 19BR004845; RJ; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Oct-2019	20-Oct-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female dog of 4 kg (other signalment is unknown) was treated with FRONTLINE PLUS DOG S (FL) (lot, exp date, route and location are unknown), applied by the reporter on 18 Oct 2019. 48 hours post product application, the owner noticed that her pet remained scratching itself. No ectoparasite was reported. Environment treated with Butox®. No further information is available. UPDATE 25 OCT 2019 - The owner was contacted and reported that Kira, a female small crossbred dog of 3 months old and 4 kg, was treated, for the first time, with one dose of FL (topical, btw the shoulder blades), for flea/tick treatment. Although ectoparasites are not seen, Kira is still scratching herself. The owner believes that her pet presents itching due to fleas (although she cannot see them). Environment treated with Butox®. No further information is expected.
21-Oct-2019	UAE; 19BR004855; SE; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 dogs of unknown signalment were treated with FRONTLINE (FL) (unsunstantiated, lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Oct 2019*), for flea

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ED_005739D_00014391-00034

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					treatment. The animals remained with fleas. So, she purchased another product, but the current status of the animals is unknown. FL was applied for the first time on date not specified. There is a cat in this household with similar issue (see case 19BR004856). No further information is expected.
21-Oct-2019	UAE; 19BR004856; SE; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 1 cat of unknown signalment was treated with FRONTLINE (FL) (unsunstantiated, lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Oct 2019*), for flea treatment. The animal remained with fleas. So, the owner purchased another product and the current status of the pet is unknown. FL was applied for the first time on date not specified. There are 3 dogs in this household with similar issue (see case 19BR004855). No further information is expected.
18-Oct-2019	UAE; 19BR004857; -; Brazil	**Species:** Canine **Breed:** Poodle (Toy) **Sex:** M **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 4 kg	1	1	1	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	01-Oct-2018*	0 Day(s)	D-A	Suspected Lack of Efficacy: As reported by the pet owner, Pipo, a male Poodle of 15 years old and 4 kg, received FRONTLINE (Unsubstantiated; lot and exp date is unknown; unknown route) (FL) applied by the reporter on an unknown date (1 Oct 2018*) for unknown reason. Lack of efficacy was suspected because Pipo was diagnosed with Tick Borne-Disease by DVM. He also presented hair loss and 'got purple' due to the disease. The dog received treatment, got recovered and came to death on unknown date (1 Jan 2019*) due to the sequels. Environmental factors were not known. This is the extent of the information available.
21-Oct-2019	UAE; 19BR004859; PR; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Month(s) **Weight:** 2.9 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Oct-2019	19-Oct-2019	0 Day(s)	D-B	Suspected Adverse Event: As reported by the pet owner, Yumi, a female mixed breed cat of 10 months old and 2.9 kg, was treated, for the first time, with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 19 Oct 2019, for flea control. The pet was in good health prior to FL and has no history of adverse reactions. Around 3 - 4 hours post FL application, the pet experienced lethargy, tremor, spasms and convulsion. She was bathed, but tremor and convulsion have continued. yumi was taken to the vet and remains hospitalized (details were not provided). The environment was treated with a product against ectoparasites, however, the owner assures that the pet had no contact with the product. The pet has recovered. There is one more cat in this household that was treated with FL SPOT-ON and it had no issue. No further information is available. UPDATE 28 Oct 2019 – The veterinarian was contacted and informed that on 19 Oct 2019 Yumi was presented to the vet office with tachycardia, nystagmus, trembling, hyperreflexia and incoordination. Fluid therapy, ranitidine and ondansetron were provided for treatment while the animal was hospitalized and 2 days later (21 Oct 2019) Yumi fully recovered. Poisoning is the main DVM's suspicion and he attributed it to FL incorrect use (according to the reporter, the product was incorrectly administered and the cat may accidentaly licked it). He added that

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* indicates Approximate date or weight.

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ED_005739D_00014391-00035

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											the owners did not inform him regarding the environmental treatment issue. No further information is available.
21-Oct-2019	UAE; 19BR004867; PR; Brazil	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 20 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	18-Oct-2019	18-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Maylon, a male large crossbred dog of 6 years old and 20 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (002/18A, unknown exp date, topical, parts of the body), applied by the reporter on 18 Oct 2019, for flea treatment. The owner believes that FL is not working because Maylon remains with fleas. Environment not treated. There are 2 animals (species was not informed) in this household that have no issue and it is unknown if they were treated. No further information is expected.
21-Oct-2019	UAE; 19BR004868; -; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 4.9 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Oct-2019	21-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Emanueli, a female Yorkshire of 4 years old and 4.9 kg, was treated with one vial of FRONTLINE PLUS DOG S (022/18A, unknown exp date, topical, btw the shoulder blades), applied by the reporter on 15 Oct 2019, for flea/ tick control. Some days post FL application, the owner noticed some fleas on her pet. Environment treated with Butox®. FL has been applied monthly with no issue since date not specified (2016*). No further information is expected.
21-Oct-2019	UAE; 19BR004876; RJ; Brazil	**Species:** Canine **Breed:** Pit Bull **Sex:** M **Sex qualifier:** Unknown **Age:** 27.00 Month(s) **Weight:** 35 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Oct-2019	12-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Chico, a male Pit Bull of 27 months old and 35 kg, was treated with one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 12 Oct 2019, for tick treatment. The owner still sees ticks on his pet. Environment not treated. FL has been applied every 6 months since date not specified. No further information is expected.
22-Oct-2019	UAE; 19BR004878; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 18 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	05-Aug-2019*	23-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Estopa, a male medium crossbred dog of 8 years old and 18 kg, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on date not specified (5 Aug 2019*), for flea/tick control. The pet got fleas approximately 7 weeks after treatment, so another administration was made on 5 Oct 2019. However, the pet remains with fleas. Environment not treated. FL has been applied with no issue every 2 months since date not specified. There is a cat that received FL PLUS CATS with the same issue in this house (see case 19BR004879). No further information is expected.

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ED_005739D_00014391-00036

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					
22-Oct-2019	UAE; 19BR004879; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Aug-2019*	23-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Faisca, a male mixed breed cat of 3 years old and 8 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on date not specified (5 Aug 2019*), for flea/tick control. The pet got fleas approximately 7 weeks after treatment, so another administration was made on 5 Oct 2019. However, the pet remains with fleas. Environment not treated. FL has been applied every 2 months since date not specified. There is a dog that received FL PLUS DOG M with the same issue in this house (see case 19BR004878). No further information is expected.
22-Oct-2019	UAE; 19BR004885; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Oct-2019	12-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Jade, a female mixed breed cat of 4 years old and 3 kg, was treated, for the first time, with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 12 Oct 2019, for flea treatment. However, the pet remains with fleas. Environment treated with Butox®. There is another cat in this household that was treated with a different product and there are two dogs that were treated with NEXGARD and they have no issue. No further information is expected.
22-Oct-2019	UAE; 19BR004887; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	15-Oct-2019*	2 Week(s)	D-D	Suspected Adverse Event: As reported by the pet owner via social media, one cat of unknown signalment received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Oct 2019 - chosen at random). After product application (exact time to onset is unknown), the pet was not 'feeling well' (details are unknown). The current status of the animal is unknown. This is the extent of the information available.
21-Oct-2019	UAE; 19BR004889; RS; Brazil	**Species:** Feline **Breed:** Turkish Angora **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Oct-2019	15-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Tilápia, a female Turkish Angora of 2 years old and 3 kg, received 1 dose of FRONTLINE SPOT-ON CATS (batch and exp. date unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 15 Oct 2019 for flea treatment. Lack of efficacy is suspected because Tilápia remains with fleas . Environment not treated. No further information is available.
22-Oct-2019	UAE; 19BR004907; SP; Brazil	**Species:** Feline **Breed:** Feline (unknown)	1	1	0	**Product used:** FIPRONIL SPRAY	01-Oct-2019*	01-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female kitten of unknown signalment was treated with FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown) for the

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ED_005739D_00014391-00037

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					first time, applied by the reporter on date not specified (1 Oct 2019*), for flea treatment. However, the pet owner continued to see fleas on her pet. So, she applied FL again on date not informed (15 Oct 2019*) and the cat remains with fleas. There are other cats in this household that were not treated. No further information is available.
23-Oct-2019	UAE; 19BR004911; SP; Brazil	**Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 5.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Aug-2019*	15-Oct-2019	N/A	D-D	Suspected Lack of Efficacy: As reported by the pet owner, Mel, a female Poodle of 7 years old and 5.5 kg, received one pipette of FRONTLINE PLUS DOG S (lot and exp date is unknown; topical, btw the shoulder blades) (FL), applied by the reporter on 15 Aug 2019* for flea/tick control. Lack of efficacy is suspected because Mel got fleas on 15 Oct 2019, so another application on FL was made on the same date and the dog remains with fleas. FL has been administered every 2 months (first administration date not provided) with no issue. Environment treated with Butox®. No further information is available.
23-Oct-2019	UAE; 19BR004912; SP; Brazil	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** X **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 24 - 28.5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	11-May-2019*	15-May-2019*	N/A	D-D	Suspected Lack of Efficacy: As reported by the pet owner, 2 crossbreed dogs (Ozzy, male, 9 years old, approx. 24 kg; Pipa, female, 6 years old, 28.5 kg) received one pipette of FRONTLINE PLUS DOG L (lot and exp date is unknown; topical, btw the shoulder blades and on the tail) (FL) each, applied by the reporter on 11 May 2019* for flea/tick control. Lack of efficacy is suspected because the dogs got fleas after treatment. New applications of FL were made on 11 Jul 2019* and on 11 Sep 2019 and the dogs remain with fleas. FL has been administered every 2 months for the last 18 months and previously used to be administered every 3 months (first administration date not provided) with no issue. Environment treated with product containing Fipronil. There are 2 cats that were treated with FRONTLINE PLUS CATS with the same issue living in this house (see case 19BR004913). No further information is available.
23-Oct-2019	UAE; 19BR004913; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 1.50 Year(s) **Weight:** 3.2 - 3.8 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	01-Apr-2019*	15-May-2019*	N/A	D-D	Suspected Lack of Efficacy: As reported by the pet owner, 2 female crossbreed cats (Lávuli, 2 years old, 3.5-3.8 kg; Aghata, 1.5 years old, 3.2 kg) received one pipette of FRONTLINE PLUS CATS (lot and exp date is unknown; topical, btw the shoulder blades and on the tail) (FL) each, applied by the reporter on 1 Apr 2019* for flea/tick control. Lack of efficacy is suspected because the cats got fleas after treatment. New applications of FL were made on 1 Jun 2019* and on 1 Aug 2019* and the pets remain with fleas. FL has been administered every 2 months (first administration date not provided) with no issue. Environment treated with product containing Fipronil. There are 2 dogs that were treated with FRONTLINE PLUS DOG L with the same issue living in this house (see case 19BR004912). No further information is available.

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ED_005739D_00014391-00038

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
23-Oct-2019	UAE; 19BR004919; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the pet owner, a female dog of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and administration site unknown) (FL), administered by the reporter on an unknown date (1 Oct 2019 - chosen at random) for flea treatment. Lack of efficacy is suspected because the pet remained with fleas. The current status of the animal is unknown. Environmental factors are not known. This is the extent of the information available.
24-Oct-2019	UAE; 19BR004932; PR; Brazil	**Species:** Feline **Breed:** Siamese **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Month(s) **Weight:** 1.8 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Oct-2019	22-Oct-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Safira, a female Siamese cat of 5 months old and 1.8 kg, received one pipette of FRONTLINE SPOT-ON CATS (FL) (lot and exp unknown, topical, btw the shoulder blades) for the first time, applied by the reporter on 14 Oct 2019 for flea treatment. Lack of efficacy is suspected because on 22 Oct 2019 Safira started to itch because she is infested with fleas again. There is a dog in the same household that has been treated with FRONTLINE with no issue. Environment not treated. No further information is available.
24-Oct-2019	UAE; 19BR004935; RS; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Month(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Oct-2019	22-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lola, a female Shih Tzu of 5 months old and 5 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown, topical, btw the shoulder blades) for the first time, applied by the reporter on 22 Oct 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with fleas , and ticks also started to be observed. Lola is bathed weekly. There are other dogs in the same household that were treated with Pulgoff® with no issue. FRONTLINE was used on her animals in the past with no issue. Environment partially treated with Butox®. No further information is available.
23-Oct-2019	UAE; 19BR004936; -; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 5.5 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Oct-2019	23-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a dog of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot and exp unknown, topical, unknown application site), applied by the reporter on unknown date (1 Oct 2019 – chosen at random) for flea treatment. Lack of efficacy is suspected because 20 days post application fleas were observed on the dog. Environmental factors are not known. This is the extent of the information available. UPDATE 5 NOV 2019 - The reporter informed that Manu, a female Yorkshire of 5 years old and 5.5 kg received 1 vial of FRONTLINE SPOT-ON DOGS S (lot and exp date unknown, topical, btw the shoulder blades) on 20 Oct 2019 for flea/tick control. Lack of efficacy is suspected because the pet got fleas after treatment and remains infested. Manu is bathed twice a week. FL has been administered monthly for the last 5 years (since 2014*) with no issue. Environment treated with Butox®. No further information is expected.
24-Oct-2019	UAE; 19BR004937; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE	01-Oct-2019*	22-Oct-2019*	3 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 cats of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and administration site unknown), administered by the reporter on unknown date (1 Oct

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ED_005739D_00014391-00039

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					2019 – chosen at random). According to the reporter, FRONTLINE is not as effective as it used to be because fleas became resistant to the product and it was no longer effective 3 weeks post administration. Environment treated with unknown products. This is the extent of the information available.
24-Oct-2019	UAE; 19BR004940; RS; Brazil	**Species:** Feline **Breed:** Feline various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 3 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Oct-2019	21-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 cats (Chiquinho, male, Siamese, 1 year old, 3 kg; Linda, female, Persian, 6 years old, 3 kg) received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp unknown, topical, btw the shoulder blades) each, for the first time, applied by the reporter on 21 Oct 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. The cats use to be bathed every 15 days. Environment not treated. No further information is available.
25-Oct-2019	UAE; 19BR004944; RS; Brazil	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Sep-2019*	02-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Suzi, a female Poodle of 13 years old and 5 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown, topical, btw the shoulder blades), administered by the reporter on late September (25 Sep 2019*) for flea/tick control. Lack of efficacy is suspected because 1 week after treatment the reporter started to visualize fleas and ticks on the dog. So, on 25 Oct 2019 FRONTLINE PLUS (unsubstantiated) was administered on Suzi and no more ectoparasites were visualized. FL was used in the past (every 3 months, first administration date not provided) with no issue. Suzi is bathed every 15 days. Environment not treated. There is another dog in the same household that was treated with FRONTLINE PLUS (unsubstantiated) with no issue. No further information is available.
25-Oct-2019	UAE; 19BR004959; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 10 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Oct-2019	17-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Floquinho, a male crossbreed cat of 8 years old and 10 kg received one pipette of FRONTLINE SPOT-ON CAT (FL) (lot and exp unknown, topical, btw the shoulder blades), applied by the reporter on 17 Oct 2019 for flea treatment. Lack of efficacy is suspected because the Floquinho remains with fleas. FL was administered approx. 4 years ago with no issue. There is another cat in the same household that has not been treated. The cats are bathed monthly. Environment treated with Butox®. No further information is available.
25-Oct-2019	UAE; 19BR004960; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s)	3	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** PO-Oral **Was the**	25-Oct-2019	25-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Suzy, a female mixed breed cat of 6 months old and unknown weight licked her two kittens that were treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown), applied by the reporter on 25 Oct 2019, for flea treatment. Some hour later, Susy presented with nausea. No vet care was provided. The other two cats had no reaction. SLOE case reported on 19BR004961. No further information is available.

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* indicates Approximate date or weight.

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ED_005739D_00014391-00040

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				**product used ok?:** No (Route not indicated / recommended)					
25-Oct-2019	UAE; 19BR004961; SP; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 3.00 Day(s) **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	25-Oct-2019	25-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 kittens of 3 days old (other signalment is unknown) were treated, for the first time, with FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown), applied by the reporter on 25 Oct 2019, for flea treatment. The number of fleas has increased. Environment not treated. SAE case regarding the mother of the kittens reported on BRA-BIAHPV1P-19BR004960. No further information is expected.
26-Oct-2019	UAE; 19BR004971; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 3 - 4.5 kg*	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	19-Oct-2019*	19-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 crossbred cats of mixed sex, 1 year old to 5 years and 3 kg to 4.5 kg, were treated with FRONTLINE PLUS CATS (FL) (lot, exp date, route and location are unknown), applied on each one by the reporter around 19 Oct 2019, for unknown reason. The animals remain scratching themselves. No ectoparasite was reported. Environment not treated. FL was applied around 1 year ago and it was effective. No further information is available.
27-Oct-2019	UAE; 19BR004973; SP; Brazil	**Species:** Canine **Breed:** English Bulldog **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 38 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Sep-2019*	18-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Thor, a male English Bulldog of 8 years old and 38 kg, was treated with one vial of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 18 Sep 2019, for flea treatment. However, the pet remains with fleas. Environment not treated. FL has been applied twice a year (months not specified). No further information is expected.
26-Oct-2019	UAE; 19BR004980; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one cat of unknown signalment was treated with FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Oct 2019*). However, the product was not effective (details are unknown). This is the extent of the information available.
26-Oct-2019	UAE; 19BR004981; MG; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products**	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of dogs were treated with FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not

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ED_005739D_00014391-00041

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** 13.00 Month(s) **Weight:** 40 kg				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					specified (1 Oct 2019*). However, the product was not effective (details are unknown). This is the extent of the information available. UPDATE 1 NOV 2019 - The owner was contacted and reported that her two dogs (Liliti, a female Rottweiler of 13 months old and 40 kg; Maila, a female Akita of 17 months old and 40 kg), were treated with one vial of FRONTLINE SPOT-ON DOGS L (topical, btw the shoulder blades), applied to each dog, for flea treatment. However, the animals remain with fleas. Environment treated with Butox®. FL has been applied every 6 months since date not specified. No further information is expected.
26-Oct-2019	UAE; 19BR004982; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one cat of unknown signalment was treated with FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Oct 2019*). However, the product was not effective (details are unknown). This is the extent of the information available.
26-Oct-2019	UAE; 19BR004985; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one cat of unknown signalment was treated with FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Oct 2019*). However, the product was not effective (details are unknown). Similar case with a dog that received FRONTLINE with the same issue reported on 19BR004986. This is the extent of the information available.
26-Oct-2019	UAE; 19BR004986; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one dog of unknown signalment was treated with FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Oct 2019*). However, the product was not effective (details are unknown). Similar case with a cat that received FRONTLINE with the same issue reported on 19BR004985. This is the extent of the information available.
27-Oct-2019	UAE; 19BR004988; -; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	22-Oct-2019	22-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female dog of unknown signalment received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp. date, route and location are not known), applied by the reporter on 22 Oct 2019 for flea treatment. Lack of efficacy is suspected because the dog remains with fleas and it remains itching due to the ectoparasite infestation. Environmental factors are not known. This is the extent of the information available. UPDATE 31 Oct 2019 – The pet owner was contacted and reported the animal signalment – Serena, female crossbred dog of 12 years old and 8 kg*. FL was applied topically (btw the shoulder blades). The dog is still with fleas. FL has been administered every approx. 1-2 months. Environment not treated.

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* indicates Approximate date or weight.

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ED_005739D_00014391-00042

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					No further information is available.
24-Oct-2019	UAE; 19BR004991; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one cat of unknown signalment was treated with FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Oct 2019*), for flea treatment. However, the pet remained with fleas. This is the extent of the information available. UPDATE 27 NOV 2019 - The owner informed via social media that she has more than one cat and FL was applied on them and they remained with fleas. More details were not provided. No further information is known.
26-Oct-2019	UAE; 19BR004993; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, three dogs of unknown signalment were treated with FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Oct 2019*), for flea/tick treatment. The animals remain with ectoparasites. This is the extent of the information available.
25-Oct-2019	UAE; 19BR004994; RS; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 2 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Sep-2019*	Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a dog of unknown signalment, received FRONTLINE (usubstantiated) (FL) (lot, exp. date, route and location are not known), applied by the reporter on a date not specified (1 Oct 2019 – chosen at random). According to the reporter, the product was not effective and lack of efficacy is suspected because FL 'didn't kill any fleas'. The current status of the animal is unknown. Environmental factors are not known. This is the extent of the information available. UPDATE 12 NOV 2019 - The owner was contacted and reported that Serena, a female Yorkshire of 5 years old and 2 kg, was treated with one vial of FRONTLINE PLUS DOG S (topical, btw the shoulder blades), applied by the reporter 2 months ago (Sep 2019*), for flea treatment. However, the pet remained with fleas. So, 15 days post product application (Oct 2019*), Ectopar® was administered and the pet is currently free of fleas. Environment treated with amitraz. The owner mentioned that she has 11 dogs in her household and all of them were also treated with FRONTLINE (unsubstantiated) and they remained with fleas (SLOE case reported on BRA-BIAHPV1P-19BR005323). She also complained that FRONTLINE (unsubstantiated) was applied in the past and the product was not effective (SLOE case reported on BRA-BIAHPV1P-19BR005324). No further information is expected.
26-Oct-2019	UAE; 19BR004998; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one cat of unknown signalment received FRONTLINE (FL) (NG) (lot, exp date, route and location), applied by the reporter on date not specified (Oct 2019*). The product was not effective. This is the extent of the information available.

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ED_005739D_00014391-00043

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					
31-Oct-2019	UAE; 19BR005000; RJ; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 11.00 Month(s) **Weight:** 1.5 - 3 kg	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Oct-2019	19-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two male mixed breed cats of 11 months old (Preto of 3 kg and Branco of 1.5 kg) were treated, for the first time, with one vial of FRONTLINE SPOT-ON CAT (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied on each one by the reporter on 19 Oct 2019, for flea treatment. However, the animals remain with fleas. Environment treated with Talfon®. No further information is expected.
01-Nov-2019	UAE; 19BR005002; RS; Brazil	**Species:** Canine **Breed:** Boxer **Sex:** F **Sex qualifier:** Unknown **Age:** 55.00 Day(s) **Weight:** 3.3 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Contraindication per label)	21-Oct-2019	21-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Ice, a female Boxer of 55 days old and 3.3 kg, was treated, for the first time, with one vial of FRONTLINE SPOT-ON DOGS S (FL) (019/18A, Aug 2020, topical, btw the shoulder blades), applied by the reporter on 21 Oct 2019, for flea/tick treatment. However, the pet remains with ectoparasites. Environment treated with Butox®. No further information is expected.
28-Oct-2019	UAE; 19BR005006; SP; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 6.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Oct-2019	28-Oct-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Leo, a male Shih Tzu of 2 years old and approx. 6.5 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date are unknown; topical, btw the shoulder blades) for the first time, applied by the reporter on 25 Oct 2019 for flea control. Lack of efficacy is suspected because fleas started to be seen on Leo on 28 Oct 2019. Environment not treated. No further information is available.
28-Oct-2019	UAE; 19BR005008; RJ; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 2 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	26-Oct-2019	27-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Meg Santos, a female Yorkshire of 2 months old and 2 kg, received FRONTLINE SPRAY 250 ML (FL) (004/19A, Mar/2020; topical, on the back, head and paws – off-label use) for the first time, applied by the reporter on 26 Oct 2019 for tick control. Lack of efficacy is suspected because on 27 Oct 2019 ticks started to be seen and on 28 Oct 2019 live ticks were visualized on Meg Santos. There are untreated animals (species not informed) living in this house. Environment not treated. No further information available.

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* indicates Approximate date or weight.

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ED_005739D_00014391-00044

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: No (Treatment / vaccination program not respected)					
25-Oct-2019	UAE; 19BR005009; -; Brazil	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner via social media, a female Domestic Longhair cat of unknown signalment received FRONTLINE (FL) (unsubstantiated; topical; lot, exp date and location are unknown) administered by the reporter on Oct 2019* for unknown reason. The cat experienced hair loss at the FL application site an unknown time after product administration. This is the extent of the information available.
28-Oct-2019	UAE; 19BR005011; PR; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 4 - 8 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	08-Oct-2019*	23-Oct-2019*	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 crossbreed cats (Panda, male, 2 years old, 8 kg; Osana, female, 1 year old, 4 kg), received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp. date are unknown; topical, from top of the head to base of skull) each, applied by the reporter on approx. 8 Oct 2019 for flea treatment. For 15 days the product was effective but lack of efficacy is suspected because on approx. 23 Oct 2019 new fleas were observed. FL was administered in the past (dose frequency and first administration date unknown) with no issue. There are 2 dogs of the same household treated for fleas with an unknown product. Environment not treated. This is the extent of the information available.
27-Oct-2019	UAE; 19BR005012; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	5	5	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	01-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 5 adult crossbred cats of mixed sex (other signalment is unknown) were treated with FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied on each one by the reporter on 1 Oct 2019, for flea treatment. However, the owner still sees fleas on her animals. Environment not treated. They have no outdoor access. It is unknown if the animals were treated with FL in the past. There is one more cat in this household that was treated with Comfortis® and it has no issue. No further information is expected.
27-Oct-2019	UAE; 19BR005014; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used**	Jul-2019*	Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one cat of unknown signalment was treated with FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter for 3 months (Jul 2019*, Aug 2019 and Sep 2019*) for flea treatment. However, the owner continued to see fleas on her cat. So, another product was administered and the pet is currently free of fleas. This is the extent of the information available.

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* indicates Approximate date or weight.

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ED_005739D_00014391-00045

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					
29-Oct-2019	UAE; 19BR005015; RJ; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 6 kg	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Oct-2019	14-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Loop, a male crossbreed dog of approx. 4 months old and approx. 6 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date are unknown; topical, btw the shoulder blades) for the first time, applied by the reporter on 14 Oct 2019 for tick treatment. Lack of efficacy is suspected because Loop remains with ticks. The reporter has another dog that was treated with FL no issue and it lives in other house. Environment not treated. No further information is available.
28-Oct-2019	UAE; 19BR005024; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 10.5 - 18 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Oct-2019	25-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 male dogs of 9 years old (Bartolomeu, Shih Tzu, 10.5 kg; Bulga, Shar pei, 18 kg) received one pipette of FRONTLINE PLUS DOG M (FL) (lot and exp. date are unknown; topical, btw the shoulder blades) each, applied by the reporter on 25 Oct 2019 for flea treatment. Lack of efficacy is suspected because fleas are still being seen on the dogs. There is a cat of the same household that was treated for fleas. FL was administered in the past (dose frequency and first administration date unknown) with no issue. Environment treated with Butox®. No further information is available.
27-Oct-2019	UAE; 19BR005025; RJ; Brazil	**Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Month(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female Pinscher of other signalment unknown, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and application site are unknown), applied by the reporter on date not informed (1 Oct 2019*) for tick treatment. Lack of efficacy is suspected because ticks are still being seen on the pet. There is a garden in the house but the dog does not have access. Environmental factors are not known. This is the extent of the information available. UPDATE 2 DEC 2019 – The owner was contacted and informed that July, a female Pinscher of 5 months old and approx. 3 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (topical, btw the shoulder blades) for the first time. According to the reporter, one week after administration ticks remained to be seen, so July was bathed with an unknown ectoparasiticide soap and the issue was solved. Environment treated with unknown product. No further information expected.
29-Oct-2019	UAE; 19BR005031; SP; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 10 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Oct-2019	27-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Shakira, a female crossbreed dog of 6 years old and 10 kg, received FRONTLINE SPRAY 100 ML (FL) (006/19A, exp. date unknown; topical, whole body) for the first time, applied by the reporter on 27 Oct 2019 for flea treatment. Lack of efficacy is suspected because fleas are still being seen on Shakira. Environment treated with unknown product. There is a cat that received FL with the same issue living in this house (see case 19BR005032). No further information available.

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* indicates Approximate date or weight.

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ED_005739D_00014391-00046

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
29-Oct-2019	UAE; 19BR005032; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Month(s) **Weight:** 2 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Oct-2019	27-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Theo, a male crossbreed cat of 5 months old and 2 kg, received FRONTLINE SPRAY 100 ML (FL) (006/19A, exp. date unknown; topical, whole body) for the first time, applied by the reporter on 27 Oct 2019 for flea treatment. Lack of efficacy is suspected because fleas are still being seen on Theo. Environment treated with unknown product. There is a dog that received FL with the same issue living in this house (see case 19BR005031). No further information available.
29-Oct-2019	UAE; 19BR005033; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 1.5 - 2.5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Oct-2019	25-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 cats (Simba, male, crossbreed, 6 months old, 1.5 kg; Nina, female, crossbreed, 1 year old, 2.5 kg) received FRONTLINE PLUS CATS (FL) (lot and exp. date unknown; topical, between the shoulder blades) for the first time, applied by the reporter on 25 Oct 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. Environment treated with K-Othrine®. No further information available.
28-Oct-2019	UAE; 19BR005034; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 12 - 15 kg	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	13-Oct-2019*	13-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 female dogs of 12 kg, 13 kg and 15 kg other signalment unknown, received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp. date unknown, route and application site are unknown), applied by the reporter on 13 Oct 2019* for flea treatment. Lack of efficacy is suspected because the dogs remain with fleas. Environment treated with Triatox®. This is the extent of the information available.
29-Oct-2019	UAE; 19BR005035; SP; Brazil	**Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 2.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Oct-2019	25-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Kiwi, a male Pinscher of 2 years old and 2.5 kg received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknown; topical, between the shoulder blades) for the first time, applied by the reporter on 25 Oct 2019 for flea treatment. According to the reporter, the amount of fleas has decreased, but lack of efficacy is suspected because Kiwi is still itching due to the ectoparasites. Environment not treated. No further information available.
28-Oct-2019	UAE; 19BR005036; -; Brazil	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F	1	1	0	**Product used:** FIPRONIL SPRAY **Other products**	17-Oct-2019	28-Oct-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Poodle of 6 years old and 6 kg, received FRONTLINE SPRAY (FL) (lot and exp. date unknown; topical, whole body) for the first time, applied by the reporter on 17 Oct

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ED_005739D_00014391-00047

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** 6.00 Year(s) **Weight:** 6 kg				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					2019 for ectoparasite control. Lack of efficacy is suspected because Mel got a tick during an outdoor walk on 28 Oct 2019. The current status of the dog is unknown. FRONTLINE (pipette, presentation usubstantiated) was administered on the past with no issue. Environment treated with Butox®. No further information available.
28-Oct-2019	UAE; 19BR005037; -; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 2 - 2.8 kg	4	4	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	15-Oct-2019	15-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 dogs of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp. date unknown, route and application site are unknown), applied by the reporter on 13 Oct 2019* for unknown reason. Lack of efficacy is suspected because fleas are being seen on the dogs. Environmental factors are not known. There are cats that were treated with FRONTLINE with the same issue living in this house (see case BRA-BIAHPV1P-19BR005038). This is the extent of the information available. UPDATE 22 NOV 2019 - The owner was contacted and reported that her 4 dogs (various breeds) from 8 months old to 16 years old, weighting from 2 kg to 2.8 kg and mixed sex, were treated, for the second time, with one vial of FRONTLINE SPOT-ON (unsubstantiated) (FL) (topical, btw the shoulder blades), applied, to each dog, on 15 Oct 2019, for flea control. It is unknown if the animals remain with fleas. Environment treated with an unknown product. FL was applied for the first time one date not specified. No further information is expected.
28-Oct-2019	UAE; 19BR005038; -; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 1.2 - 3 kg	4	4	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Oct-2019	28-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 cats of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp. date unknown, route and application site are unknown), applied by the reporter on 13 Oct 2019* for unknown reason. Lack of efficacy is suspected because fleas are being seen on the cats. Environmental factors are not known. There are dogs that were treated with FRONTLINE with the same issue living in this house (see case BRA-BIAHPV1P-19BR005037). This is the extent of the information available. UPDATE 22 NOV 2019 - The owner was contacted and reported that her 4 male crossbred cats from 6 months to 5 years old, weighting from 1.2 kg to 3 kg, were treated, for the second time, with one vial of FRONTLINE SPOT-ON CATS (FL) (012/18A, unknown exp date, topical, btw the shoulder blades), applied, to each cat, on 15 Oct 2019, for flea control. It is unknown if the animals remain with fleas. Environment treated with an unknown product. FL was applied for the first time one date not specified. No further information is expected.
28-Oct-2019	UAE; 19BR005040; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2019*	2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female dog of other signalmente unknown, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date unknown, route and application site are not known), administered by the reporter on 2 dates not informed (2019*) for unknown reason. According to the reporter, the product was not effective. Environmental factors are not known. This is the extent of the information available.

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ED_005739D_00014391-00048

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
28-Oct-2019	UAE; 19BR005041; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 cats of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date unknown, route and application site are not known), applied by the reporter on date not specified (1 Oct 2019* – chosen at random). According to the reporter, the product was not effective. Environmental factors are not known. This is the extent of the information available.
28-Oct-2019	UAE; 19BR005043; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, two cats of unknown signalment were treated with FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on Oct 2019. The owner believes that FRONTLINE is not effective (details were not provided). This is the extent of the information available.
30-Oct-2019	UAE; 19BR005048; -; Brazil	**Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 600 gms	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	20-Sep-2019	20-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Theo, a male Pinscher of 3 months old and 600 g, received FRONTLINE SPRAY 100 ML (FL) (002/18A, exp. date unknown; topical, whole body except head) for the first time, applied by the reporter on 20 Sep 2019 for flea treatment. Lack of efficacy is suspected because the pet remained with fleas, so other applications were made on unspecified dates and last application was made on 29 Oct 2019. Theo remains with fleas. Environment treated with K-Othrine® e Butox®. No further information available.
29-Oct-2019	UAE; 19BR005051; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown number of cats of unknown signalment, received FRONTLINE SPRAY (FL) (lot, exp. date, route and application site are unknown), applied by the reporter on date not informed (1 Oct 2019 – chosen at random) for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. FL was used by the reporter in the past with no issue (it is not clear if it was used on these animals). Environmental factors are not known. No further information available.
28-Oct-2019	UAE; 19BR005053;	**Species:** Feline **Breed:** Feline	10	10	0	**Product used:** FIPRONIL	Jan-2019*	Jan-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 10 cats of unknown signalment were treated with

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ED_005739D_00014391-00049

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; Brazil	(unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter for 5 consecutive months (Jan 2019* to May 2019*). However, the owner believes that the product was not working (details are unknown). She administered another product, which was effective. This is the extent of the information available.
04-Nov-2019	UAE; 19BR005055; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 6.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Oct-2019	14-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Jimmy, a male crossbred cat of 5 years old and 6.5 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 14 Oct 2019, for flea treatment. However, the pet remains with fleas. Environment treated with Butox®. The pet has no outdoor access. No further information is expected.
29-Oct-2019	UAE; 19BR005057; RJ; Brazil	**Species:** Canine **Breed:** Rottweiler **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** 33 - 39 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Oct-2019	29-Oct-2019	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two male Rottweilers (Toreto, 2 years old and 33 kg; Alafin, 9 months old and 39 kg) were treated with one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical), applied on the 'dorsal neck region' of each animal by the reporter on 17 Oct 2019, for tick control. However, 12 days post produt application, the owner started to see live ticks on her animals. The animals have outdoor access. Environment not treated. FL has been applied every 45 days since date not specified. Toreto has experienced a similar issue in the past (see case 18BR001641). No further information is expected.
30-Oct-2019	UAE; 19BR005058; RS; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 30.00 Month(s) **Weight:** 3.5 - 7 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	24-Oct-2019	24-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two dogs (Akina, a female Dachshund of 30 months old and around 3.5 kg; Pitoca, a female small crossbred dog of 5 years old and 7 kg) were treated with FRONTLINE SPRAY (001/18A, unknown exp date, topical, head - off label use, low dose) for the first time, applied by the reporter on 24 Oct 2019, for flea control. However, fleas have been found on her dogs. So, she applied FL again on 28 Oct 2019 and the animals remain with fleas. Environment treated with Butox® and Talfon®. There is one more dog in this household that was not treated. No further information is expected.
29-Oct-2019	UAE; 19BR005063; SP; Brazil	**Species:** Feline **Breed:** Feline (unknown)	10	10	0	**Product used:** FIPRONIL SPOT ON CAT	18-Oct-2019	18-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 10 cats of unknown signalment received FRONTLINE SPOT-ON CAT (FL) (lot and exp. date unknown; topical, btw the shoulder

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ED_005739D_00014391-00050

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					blades) each, for the first time, applied by the reporter on 18 Oct 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. Environment has been treated every 6 months by a specialized company (last treatment on 13 Oct 2019). There are 4 dogs that received FRONTLINE SPOT-ON (unsubstantiated) with the same issue living in this house (see case 19BR005064). No further information available.
29-Oct-2019	UAE; 19BR005064; SP; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	18-Oct-2019	18-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 dogs of unknown age (2 female crossbred of 14 kg; 1 male Yorkshire Terrier of 4.5 kg and 1 male Poodle of 4.5 kg), received FRONTLINE SPOT-ON (unsubstantiated) (FL) (lot and exp. date unknown; topical, btw the shoulder blades), each, for the first time, applied by the reporter on 18 Oct 2019 for flea treatment. Lack of efficacy is suspected because the dogs remain with fleas and are itching due to the ectoparasites. Environment has been treated every 6 months by a specialized company (last treatment on 13 Oct 2019). There are 10 cats that received FRONTLINE SPOT-ON CAT with the same issue living in this house (see case 19BR005063). No further information available.
30-Oct-2019	UAE; 19BR005071; SP; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** 3.5 - 5 kg	4	4	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	05-Oct-2019	05-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 cats (2 male cats of 5 kg, 1 female cat of 3.5 kg and 1 cat of unknown gender of 4 kg), received FRONTLINE SPRAY 250 ML (FL) (lot and exp. date unknown; topical, btw the shoulder blades; off-label use, low dose), applied by the reporter on 5 Oct 2019 for flea treatment. Lack of efficacy is suspected because the pets remained with fleas, so other two applications were made on 20 Oct 2019 and on 23 Oct 2019. The cats remain with fleas. In addition, the pets have contact with stray cats. FL wad administered on the past (dose frequency and first administration date not provided) with no issue. Environmental factors are not known. No further information available.
29-Oct-2019	UAE; 19BR005075; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a dog of unknown signalment received FRONTLINE PLUS (unsubstantiated; lot, exp date, route and location are unknown) administered by the reporter on Oct 2019 for flea treatment. Lack of efficacy is suspected because the animal remains with fleas. This is the extent of the information is available.
30-Oct-2019	UAE; 19BR005079; SP; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	09-Oct-2019	09-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Golias, a male Yorkshire Terrier of 7 years old and 6 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknown; topical, btw the shoulder blades), applied by the reporter on 9 Oct 2019 for flea treatment. Lack of efficacy is suspected because Golias remains with fleas. FL was administered in the past (dose frequency and first administration date not provided)

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ED_005739D_00014391-00051

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 6 kg				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					with no issue. The next door is an empty plot with a high cat population. Environment not treated. No further information available.
05-Nov-2019	UAE; 19BR005093; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2019*	2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female cat of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 2019*, for flea treatment. The owner believes that FRONTLINE is not working because because her pet always get fleas. The current status of the animal is unknown. This is the extent of the information available.
30-Oct-2019	UAE; 19BR005094; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2019*	2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one male cat of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 2019*. The owner believes that FRONTLINE is not effective (details were not provided). This is the extent of the information available.
30-Oct-2019	UAE; 19BR005105; SP; Brazil	**Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	22-Oct-2019	23-Oct-2019	1 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Scooby, a male Pinscher of 13 years old and 3 kg, received FRONTLINE SPRAY 100 ML (FL) (006/19A, exp date is unknown, topical, some parts of the body, low dose – off-label use) for the first time, administered by the reporter on 22 Oct 2019 for flea treatment. Scooby was in good health prior to product administration. On 23 Oct 2019 apathy and bloody diarrhea were experienced by Scooby. The DVM was contacted by phone and recommended the use of Dramin® (3 drops, PO, BID) and Buscopan® (3 drops, PO, BID). On 25 Oct 2019 the apathy improved, however, the diarrhea is ongoing. FRONTLINE® (pipette presentation) has been administered in the past with no issue. There is no history of AEs to other products in the past. No further information is available.
30-Oct-2019	UAE; 19BR005111; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous	30-Oct-2019	30-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Farofa, a male crossbred dog of 9 months old and 17 kg, received FRONTLINE SPOT-ON DOGS M (FL) (023/18A, exp date is unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 30 Oct 2019 for flea treatment. Farofa was in good overall health prior to product administration, however, he was already experiencing intense itching due to the ectoparasite infestation. Intense itching and erythema at the

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* indicates Approximate date or weight.

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ED_005739D_00014391-00052

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Month(s) **Weight:** 17 kg				**Was the product used ok?:** Yes					application site and on the front paws was experienced by Farofa shortly after receiving FL. A lesion also appeared at the application site due to the itching. The dog was bathed and the itching improved but it was not informed if the other symptoms are still ongoing. No further information is available.
31-Oct-2019	UAE; 19BR005119; -; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** 3.9 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	22-Oct-2019	22-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Thor, a male crossbreed dog of 9 months old and 3.9 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp. date unknown; topical, from btw the shoulder blades to medium back) for the first time, applied by the reporter on 22 Oct 2019 for flea treatment. Lack of efficacy is suspected because Thor remains with fleas. Environment treated with Butox®. No further information available.
31-Oct-2019	UAE; 19BR005132; SP; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	Apr-2019*	Apr-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Maju, a female Shih Tzu of approximately 6 months old, received FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, back, paws and belly) administered by the reporter around 6 months ago (Apr 2019*) for tick treatment. Lack of efficacy is suspected because the pet remained with ticks, so NEXGARD (unsubstantiated) was administered on date not informed (May 2019*) and no more ticks were visualized. Environmental factors are not known. Same patient presented vomiting 2 times post NEXGARD administration (see SAE cases 19BR005130 and 19BR005131). This is the extent of the information available for now.
31-Oct-2019	UAE; 19BR005136; RS; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	31-Oct-2019	31-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Amy, a female cat of unknown breed, 2 years old* and 4 kg*, received FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, base of skull and btw the shoulder blades) for the first time, administered by the reporter on 31 Oct 2019 for unknown reason. Intense itching, erythema and alopecia at the application site were experienced by Amy approx. 1 hour post FL use. Babosa extract was administered at the application site and 30 minutes later the pruritus improved. The application site erythema improved on 1 Nov 2019 and the alopecia is ongoing. No further information is available.
31-Oct-2019	UAE; 19BR005138; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** -	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female dog of other signalment unknown, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and application sit are unknown), applied by the reporter on unspecified date (1 Oct 2019 – chosen at random) for ectoparasite control. Lack of efficacy is suspected because ticks started to be seen on the pet after treatment. The current status of the animal is unknown.

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ED_005739D_00014391-00053

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products **Route:** unknown **Was the product used ok?:** Unknown to Company					Environmental factors are not known. No further information available.
01-Nov-2019	UAE; 19BR005139; SP; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Oct-2019	25-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Princesa, a female Yorkshire of 4 years old and 3 kg, was treated, for the first time, with one vial of FRONTLINE SPOT-ON DOG S (019/18B, Aug 2020, topical, btw the shoulder blades), applied by the reporter on 25 Oct 2019, for flea treatment. However, the pet remains with fleas. Environment not treated. No further information is expected.
06-Nov-2019	UAE; 19BR005143; PR; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 4.000 - 7 kg*	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Oct-2019	22-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two male crossbred cats (Eliot, 4 months old and 4 kg*; Simba, 7 months old and 7 kg) were treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter, on each cat, on 22 Oct 2019, for flea treatment. However, the animals remain with fleas. Environment not treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). There are two dogs in this household that were treated with Bravecto® and they have no issue. No further information is expected.
01-Nov-2019	UAE; 19BR005145; SP; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 10.2 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Oct-2019	19-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Frederico, a male crossbreed dog of 15 years old and 10.2 kg, received one pipette of FRONTLINE SPOT-ON DOGS M (FL) (lot and exp. date unknown; topical, btw the shoulder blades), applied by the reporter on 19 Oct 2019 for flea treatment. Lack of efficacy is suspected because Frederico remains with fleas. FL has been administered every 4 months (first administration date not provided) with no issue. Environment not treated. No further information available.
01-Nov-2019	UAE; 19BR005146; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Oct-2019	28-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Temaki, a male crossbreed cat of 4 months old and 3 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, applied by the reporter on 28 Oct 2019 for flea treatment. Lack of efficacy is suspected because Temaki remains with fleas. Environment treated with Butox®. No further information available.

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ED_005739D_00014391-00054

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
04-Nov-2019	UAE; 19BR005154; SP; Brazil	**Species:** Feline **Breed:** Persian (No Further Description) **Sex:** X **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 3.2 - 3.5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Oct-2019	29-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two Persians (Miguel, male, 7 months old and 3.5 kg; Meg, female 3 years old and 3.2 kg), were treated, for the first time, with one vial of FRONTLINE PLUS CATS (FL) (007/18A, unknown exp date, topical, btw the shoulder blades) each, applied by the reporter on 29 Oct 2019, for flea treatment. However, the number of fleas has increased. Environment not treated. No further information is expected.
04-Nov-2019	UAE; 19BR005160; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 3 - 5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Nov-2019	03-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 dogs (Aquiles, male, Lhasa Apso, 5 years old, 5 kg; Agnes, female, Yorkshire Terrier, 4 years old, 3 kg) received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknown; topical, btw the shoulder blades), each, for the first time, applied by the reporter on 3 Nov 2019 for flea treatment. According to the reporter, the product was not effective. Environment treated with Butox®, unknow powder and unknown spray for flea treatment. No further information available.
04-Nov-2019	UAE; 19BR005162; -; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	23-Oct-2019	23-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via retailer, Neném, a male crossbred cat of 10 years old and 3 kg, was treated with FRONTLINE SPOT-ON CATS (FL) (lot, exp date, route and location are unknown), applied by the reporter on 23 Oct 2019, for flea treatment. However, the owner continues to see fleas on her pet. The pet has no outdoor access. This is the extent of the information available.
04-Nov-2019	UAE; 19BR005165; SP; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 2 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	01-Oct-2019*	01-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lala, a female cat of 2 kg and other signalment unknown, received one pipette of FRONTLINE SPOT-ON CAT (FL) (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, applied by the reporter on date not specified (1 Oct 2019* - chosen at random) for flea treatment. Lack of efficacy is suspected because the pet remained with fleas. On 23 Oct 2019* FL was administered for the second time and on 25 Oct 2019* fleas continued to be seen. Environment treated with unknown product. No further information available. UPDATE 25 NOV 2019 – The owner contacted BIAH and reported that 'live and big fleas ' are still being seen on the cat. In addition, fleas are also being seen on the environment. According to the reporter, the environment was treated once, before adopting the cat.
02-Nov-2019	UAE; 19BR005171; SC; Brazil	**Species:** Canine **Breed:** Canine	1	1	0	**Product used:** FIPRONIL 10%/S	05-Oct-2019*	05-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one dog of unknown signalment, received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp. date, route and application site are

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ED_005739D_00014391-00055

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		(unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					unknown), applied by the reporter on date not specified (5 Oct 2019*) for flea treatment. Lack of efficacy is suspected because the dog remains with fleas. There are two other dogs of the same household treated for fleas with unknown product. Environment treated with unknown product. This is the extent of the information available.
01-Nov-2019	UAE; 19BR005172; RS; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 4.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Sep-2011*	15-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female longhair crossbred cat of 4.5 kg and unknown age, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date, topical, btw the shoulder blades) administered by the reporter on 15 Sep*, 30 Sep* and 25 Oct 2019* for flea treatment. Lack of efficacy is suspected because Mel remains with fleas and she is intensely scratching herself due to the ectoparasite infestation. FL has been administered approx. every 6 months since Sep 2011* with no issue. According to the reporter, there are an intense flea infestation occurring in the neighborhood. Environment not treated. Another SLOE case involving 2 dogs of a reporter's family member was reported on BRA-BIAHPV1P-19BR005173. No further information is available.
01-Nov-2019	UAE; 19BR005173; RS; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 20 kg	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Dec-2017*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by a person related to the pet owner, 2 male dogs (Diego, Labrador Retriever, 2 years old, 20 kg*; Zeus, crossbred dog, 5 years old, 20 kg*) received FRONTLINE (FL) (unsubstantiated; lot, exp date, route and location are unknown) administered by the reporter on Oct 2019* for unknown reason. Lack of efficacy is suspected because ticks are being found on the dogs. FL has been administered monthly for years (since Dec 2017*) with no issue. Environmental factors are not known. Another SLOE case involving 1 cat owned by the reporter was reported on BRA-BIAHPV1P-19BR005172. No further information is available.
02-Nov-2019	UAE; 19BR005175; RS; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 1.40 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Oct-2019	29-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Bidu, a male crossbred dog of 1.4 years old and 4 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on the afternoon of 29 Oct 2019 for flea treatment. Bidu was in good overall health prior to product administration. Also on 29 Oct 2019, at night, Bidu started to experience vomiting, diarrhea, apathy and anorexia. He was taken to the veterinarian and, according to the reporter, poisoning was suspected. Vitamins and Mercepton® injectable were provided for treatment. The symptoms lasted for 1 week (date of recovery – 5 Nov 2019). No further information is available.
04-Nov-2019	UAE; 19BR005191; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the**	Sep-2019*	Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a cat of unknown signalment received FRONTLINE (unsubstantiated; lot, exp date, route and location are unknown) administered by the reporter on Sep 2019* for unknown reason. According to the reporter, the product was not effective. This is the extent of the information available for now.

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ED_005739D_00014391-00056

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					
04-Nov-2019	UAE; 19BR005194; SP; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 7.50 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Oct-2019	03-Nov-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mia, a female crossbred dog of approx. 7.5 years old and 5 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date, topical, btw the shoulder blades) for the first time, administered by the reporter on 18 Oct 2019 for tick treatment. Lack of efficacy is suspected because since 3 Nov 2019 ticks returned to be found on Mia and she remains scratching herself due to the ectoparasite infestation. Environment not treated. Another SLOE case involving 2 cats from same household was reported on BRA-BIAHPV1P-19BR005195. No further information is available.
04-Nov-2019	UAE; 19BR005195; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 1.5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Oct-2019	18-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 male crossbred cats of approx. 1.5 kg (Mushu, 7 months old; Panthru, 8 months old) received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date, topical, btw the shoulder blades) for the first time, administered by the reporter on 18 Oct 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with live fleas since product administration and they remain scratching themselves due to the ectoparasite infestation. Environment not treated. Another SLOE case involving 1 dog from same household was reported on BRA-BIAHPV1P-19BR005194. No further information is available.
02-Nov-2019	UAE; 19BR005196; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 3 - 34 kg	7	7	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jul-2019*	06-Jul-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 7 crossbreed dogs of mixed sex from 3 kg to 34 kg and from 3 years old to 9 years old, received one pipette of FRONTLINE PLUS (unsubstantiated) (FL) (lot and exp. date unknown; topical, dorsum - not specified) each, applied by the reporter on Jul 2019 (1 Jul 2019*) for ectoparasite control. Lack of efficacy is suspected because 5 days post application, after a trip for countryside, the dogs got ticks. So the pet owner administered another product (7 Jul 2019*) and no more ticks were visualized. On Sep 2019 FL was applied again and the pet owner complained that the product was not effective (SLOE case reported on BRA-BIAHPV1P-19BR005197). FL was used yearly with no issue since date not informed. Environment treated with Triatox®. No further information is available.
02-Nov-2019	UAE; 19BR005197; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 3 - 34 kg	7	7	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	Sep-2019*	Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 7 crossbreed dogs of mixed sex from 3 kg to 34 kg and from 3 years old to 9 years old, received one pipette of FRONTLINE PLUS (unsubstantiated) (FL) (lot and exp. date unknown; topical, dorsum - not specified) each, applied by the reporter on Sep 2019 for flea/tick treatment. They got ectoparasites on a trip to the countryside prior to FL. Lack of efficacy is suspected because the dogs remained with fleas and ticks. Another product was administered on date not informed (Oct 2019*) and no more ectoparasites were visualized. On Jul 2019 FL was applied and the pet owner complained that the product was not effective (SLOE case reported on BRA-BIAHPV1P-19BR005196). FL was used

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ED_005739D_00014391-00057

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					yearly with no issue since date not informed. Environment treated with Triatox®. No further information is available.
05-Nov-2019	UAE; 19BR005202; SP; Brazil	**Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 9 kg	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Nov-2019	01-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Amy, a female Pit Bull of 6 months old and 9 kg, received one pipette of FRONTLINE SPOT-ON DOG S (FL) (019/18A, exp. date unknown; topical, back - unspecified location) for the first time, applied by the reporter on 1 Nov 2019 for tick treatment. Lack of efficacy is suspected because Amy remains with ticks. There is another dog of the same household treated with FL with no issue. Environment treated with Butox®. No further information is available.
05-Nov-2019	UAE; 19BR005203; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 4.3 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Oct-2019	22-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Penélope, a female crossbred cat of 8 years old and 4.3 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (008/17, unknown exp date, topical, btw the shoulder blades), applied by the reporter on 22 Oct 2019, for flea treament. However, the pet remains with fleas. Environment treated with deltamethrin. The pet has no outdoor access. FL has been applied every 6 months since date not specified. No further information is expected.
05-Nov-2019	UAE; 19BR005204; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 4.2 - 5.8 kg	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Nov-2019	03-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 crossbreed cats (Bigos, male, 6 years old, 4.5 kg; Leopoldo, male, 8 years old, 4.2 kg; Gabi, female, 11 years old, 5.8 kg), received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp. date unknown; topical, btw the shoulder blades) each, applied by the reporter on 3 Nov 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. FL has been administered every 7 months (first administration date not provided) with no issue. Environment treated with Butox®. No further information is available.
05-Nov-2019	UAE; 19BR005211; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 12.4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Oct-2019	20-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pitty, a female medium crossbred dog of 14 years old and 12.4 kg, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 15 Oct 2019, for flea/tick control. Lack of efficacy is suspected because the pet got fleas after treatment and is scratching herself due to fleas. Also, one tick was removed from the dog a few days ago. Environment not treated. The dog has daily outdoor access. FL has been applied every month since date not specified. No further information is expected.

N/A signifies the information for this field is either not available or not applicable

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* indicates Approximate date or weight.

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Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014391-00058

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
06-Nov-2019	UAE; 19BR005214; PR; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 34.00 Month(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Oct-2019	15-Oct-2019	0 Day(s)	D-D	SUspected Lack of Efficacy Claim: As reported by the pet owner, Nala, a female crossbred cat of 34 months old and 6 kg, was treated, for the first time, with one vial of FRONTLINE PLUS CATS (007/18A, unknown exp date, topical, btw the shoulder blades), applied by the reporter on 15 Oct 2019, for flea treatment. However, the pet remains with fleas. Environment not treated. The pet has no outdoor access. No further information is expected.
05-Nov-2019	UAE; 19BR005215; SP; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 4.4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	05-Sep-2019*	22-Oct-2019	6 Week(s) 5 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female Yorkshire of 4 years old* and 4.4 kg, was treated with one vial of FRONTLINE PLUS DOG S (lot, exp date, route and location are unknown), applied by the reporter 2 months ago (5 Sep 2019*), for tick treatment. However, ticks have been found on his pet since two weeks ago (22 Oct 2019). Environment not treated. The pet has no outdoor access. No further information is expected.
05-Nov-2019	UAE; 19BR005216; SP; Brazil	**Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Month(s) **Weight:** 4 - 5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Oct-2019*	10-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two female dogs of unknown signalment were treated with FRONTLINE PLUS (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 2019*, for flea treatment. However, the owner still sees fleas on his animals. FL has been applied for the past 6 years with no issue (dose frequency is unknown and first application was not provided). This is the extent of the information available. UPDATE 12 NOV 2019 - The owner was contacted and reported that her two female Lhasa Apso (Mel, 5 years old and 5 kg; Malu, 15 months old and 4 kg) were treated with one vial of FRONTLINE PLUS DOG S (FL) (topical, btw the shoulder blades), applied to each one by the reporter on 10 Oct 2019*, for flea control. However, fleas were found on her animals and the owner always removes them, but they are still appearing. Environment not treated. FL has been applied every 3 months. No further information is expected.
05-Nov-2019	UAE; 19BR005217; PR; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown	30-Oct-2019	30-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Jorge, a male cat of 4 years old and 5 kg, was treated, for the first time, with one vial of FRONTLINE PLUS CATS (lot and exp date are unknown, topical, neck), applied by the reporter on 30 Oct 2019, for flea treatment. However, the pet remains with fleas. Environment not treated. No further information is expected.

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ED_005739D_00014391-00059

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					
06-Nov-2019	UAE; 19BR005228; SP; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	15-Sep-2019	15-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 dogs were treated with FRONTLINE (unsubstantiated) (lot, exp date, route and location), applied by the reporter on 15 Sep 2019. However, the product was not effective (details are unknown). The owner also complained that NEXGARD is not working (SLOE cases reported on BRA-BIAHPV1P-19BR005225 and BRA-BIAHPV1P-19BR005226). One of his dogs presented a SAE involving NEXGARD (case reported on BRA-BIAHPV1P-19BR005227). No further information is expected.
05-Nov-2019	UAE; 19BR005231; SP; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2014*	2014*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Kiki, a female crossbred dog of unknown age and weight, received FRONTLINE (FL) (unsubstantiated; lot, exp date, route and location are unknown) administered by the reporter 'years ago ' (2014*) for flea control. Lack of efficacy is suspected because fleas were found on the dog after product administration. Same patient experienced vomiting on 5 and 6 Nov 2019 after receiving NEXGARD® (see related cases BRA-BIAHPV1P-19BR005229 and BRA-BIAHPV1P-19BR005230). This is the extent of the information available.
06-Nov-2019	UAE; 19BR005232; ES; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 3.4 - 4.2 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	25-Oct-2019	30-Oct-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two dogs (Farelo, male, 14 years old and 4.2 kg; Uli, female, 8 years old and 3.4 kg) received FRONTLINE SPRAY (lot and exp date are unknown, topical, parts of the body), applied by the reporter on 25 Oct 2019, for flea control. However, some days after product application, the owner noticed some fleas on her animals. They were bathed, but they are scratching themselves (the owner believes that her animals still have fleas, but they are not seen anymore). Environment not treated. FL has been applied every 3 months since date not specified. No further information is expected.
06-Nov-2019	UAE; 19BR005234; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** Unknown	6	6	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Oct-2019	30-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 6 crossbred cats from 3 years old to 8 years old, mixed sex and unknown weight received one vial of FRONTLINE PLUS CATS (lot and exp date are unknown, topical, btw the shoulder blades), applied to each cat by the reporter on 27 Oct 2019, for flea control. However, some days after product application, fleas have been found her animals. Environment treated with Butox®. The cats have no outdoor access. FL has been applied every 90 days with no issue since date not specified. There is one dog in this household that was treated with FRONTLINE PLUS DOG M and it has the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005235). No further information is expected.
06-Nov-2019	UAE;	**Species:** Canine	1	1	0	**Product used:**	27-Oct-2019	27-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner,

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ED_005739D_00014391-00060

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19BR005235; SP; Brazil	**Breed:** Canine Crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 19 kg				FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					Olga, a female medium crossbred dog of 13 years old and 19 kg*, received one vial of FRONTLINE PLUS DOG M (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 27 Oct 2019, for flea control. However, some days after product application, fleas have been found on her dog. According to the owner, Olga has canine demodicosis and she is concerned because the presence of fleas may exacerbate the itchiness. Environment treated with Butox®. FL has been applied every 90 days with no issue since date not specified. There are 6 cats in this household that were treated with FRONTLINE PLUS CATS and they have the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005234). No further information is expected.
07-Nov-2019	UAE; 19BR005239; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 13 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Nov-2019	01-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lion, a male medium crossbred dog of 8 years old and 13 kg, was treated, for the first time, with one vial FRONTLINE SPOT-ON DOGS M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 1 Nov 2019, for flea treatment. However, the pet remains with fleas. Environment treated with an unknown product. No further information is expected.
06-Nov-2019	UAE; 19BR005242; SP; Brazil	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female Golden of unknown signalment was treated with FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on Oct 2019*, for flea treatment. However, the pet remained with fleas. One more vial of FRONTLINE was applied, but the pet still has fleas. There are stray cats infested with fleas around her yard. This is the extent of the information available.
07-Nov-2019	UAE; 19BR005243; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 14 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Nov-2019	06-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lili, a female crossbred dog of unknown age and 14 kg, received one pipette of FRONTLINE PLUS DOGS M (FL) (020/18A, exp date is unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 6 Nov 2019 for flea allergy dermatitis control. According to the reporter, the product was not effective. Flea/ticks were not visualized. Lili is bathed once a week. Environment is eventually treated with Butox®, however, the last treatment date was not informed. No further information is available.
06-Nov-2019	UAE; 19BR005244; SP; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female dog of unknown signalment was treated with FRONTLINE SPOT-ON DOG S (FL) (lot, exp date, route and location are unknown), applied by the reporter more than one month ago (Sep 2019*). However, the product was not effective (details are unknown). FL was applied in the past with no issue

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ED_005739D_00014391-00061

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 7.00 Year(s) **Weight:** 1.5 kg				**Route:** Topical / Cutaneous **Was the product used ok?:** Yes					(dose frequency is unknown and first administration was not provided). This is the extent of the information available. UPDATE 18 NOV 2019 - Meg, a female Yorkshire of 7 years old* and 1.5 kg*, was treated with one vial of FRONTLINE SPOT-ON DOG S (topical, btw the shoulder blades), applied by the reporter on 1 Nov 2019*, for flea treatment. However, the owner continued to see fleas on her pet. Another product was administered and Meg is currently free of fleas. Environment not treated. FRONTLINE has been applied only when the owner sees fleas on her pet. No further information is expected.
07-Nov-2019	UAE; 19BR005246; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 18.00 Month(s) **Weight:** 17 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Oct-2019	07-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Zeca, a male medium crossbred dog of 18 months old and 17 kg, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 7 Oct 2019, for flea treatment. However, the pet remains with fleas. Environment treated with Triatox®. FL was applied in the past, but the dose frequency is unknown and the first application was not provided. There are 7 more dogs in this household that were also treated with FRONTLINE PLUS DOG S and they have the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005247). In addition, there are 6 puppies that were not treated and they have no issue. No further information is expected.
07-Nov-2019	UAE; 19BR005247; SP; Brazil	**Species:** Canine **Breed:** Lhasa Apso **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** 7.5 kg	7	7	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Oct-2019	07-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 7 adults Lhasa Apso of mixed sex an 7.5 kg* were treated with one vial of FRONTLINE PLUS DOG S (lot and exp date are unknown, topical, btw the shoulder blades), applied to each dog by the reporter on 7 Oct 2019, for flea treatment. However, the pets remain with fleas. Environment treated with Triatox®. FL was applied in the past, but the dose frequency is unknown and the first application was not provided. There is 1 more dog in this household that was also treated with FRONTLINE PLUS DOG M and it has the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005246). In addition, there are 6 puppies that were not treated and they have no issue. No further information is expected.
06-Nov-2019	UAE; 19BR005249; PR; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 4.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Nov-2019	01-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a female cat of unknown signalment received FRONTLINE PLUS (FL) (unsubstantiated; lot, exp date, route and location are unknown) administered by the reporter on 1 Nov 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with live fleas and it remains intensely scratching itself. This is the extent of the information available for now. UPDATE 12 Nov 2019 – The pet owner was contacted and reported that Bebel, a female crossbred cat of 11 years old and 4.5 kg, was treated with one pipette of FRONTLINE PLUS CATS (FL) (007/18A, May 2020, topical, btw the shoulder blades). Comfortis® was administered to Bebel on 10 Nov 2019* and fleas are no longer being found since 12 Nov 2019. The itching also improved since Comfortis® administration. FL has been administered every 6 months since 2009. There is one dog of the same household and it has been treated with Bravecto®. Environment partially treated with K-Othrine® (only the house's backyard). No further information is available.

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ED_005739D_00014391-00062

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
07-Nov-2019	UAE; 19BR005255; PR; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Month(s) **Weight:** 2 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Oct-2019	15-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Stive, a male crossbred cat of 5 months old and 2 kg, received one pipette of FRONTLINE PLUS CATS (FL) (004/18A, exp date is unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 15 Oct 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with live fleas. Environment not treated. No further information is available.
07-Nov-2019	UAE; 19BR005258; SP; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 4 kg	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Oct-2019	10-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two male Yorkies of 4 kg (Nike, 10 years old; Ted, 2 years old) were treated with one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied to each dog on 10 Oct 2019, for flea treatment. However, the pets remain with fleas. Environment treated with an unknown product. The dogs have access to the front gate. FL has been applied every 3 months with no issue since date not specified. No further information is expected.
07-Nov-2019	UAE; 19BR005261; PR; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 14 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Ectoparasiticide collar from Ourofino®; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Nov-2019	04-Nov-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a dog of unknown signalment received FRONTLINE PLUS (FL) (unsubstantiated; lot and exp date are unknown) administered by the reporter on Nov 2019* for tick treatment. Lack of efficacy is suspected because the pet remains with live ticks . This is the extent of the information available for now. UPDATE 11 Nov 2019 – The pet owner was contacted and reported that Pirulito, a male crossbred dog of 7 years old and 14 kg, received one pipette of FRONTLINE PLUS DOG M (topical, from the base of skull to the back - 'as recommended') on 4 Nov 2019 for tick treatment. Prior to FL use the animal was using an ectoparasiticide collar (OuroFino company; it is unknown when he started to use it) and it was removed before using FL. After receiving FL, Pirulito returned to use the collar. FL has been administered in the past (dose frequency and 1st adm date not provided) with no issue. There is another dog of same household that has been treated with unknown product. Pirulito is taken for walking outdoors daily. Environment treated with unknown product. No further information is available.
08-Nov-2019	UAE; 19BR005263; SC; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 7 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	01-Nov-2019	08-Nov-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mauricio, a male Shih Tzu of 8 years old and 7 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 1 Nov 2019 for ectoparasite control. Lack of efficacy is suspected because the retail shop staff member found live fleas on Mauricio while he was being bathed. Environment not treated. No further information is available.

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ED_005739D_00014391-00063

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					
09-Nov-2019	UAE; 19BR005272; SP; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	30-Oct-2019*	30-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a cat of unknown signalment received FRONTLINE PLUS (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 30 Oct 2019*, for flea treatment. However, the pet remains with fleas. This is the extent of the information available.
06-Nov-2019	UAE; 19BR005275; DF; Brazil	**Species:** Canine **Breed:** French Bulldog **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 20 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Nov-2019	04-Nov-2019	0 Day(s)	D-C	Suspected Adverse Event: As reported by the pet owner, Duke, a male French Bulldog of 2 years old and 20 kg, received FRONTLINE PLUS DOGS M (FL) (lot and exp date are unknown, topical, base of skull and btw the shoulder blades) for the first time, administered by the reporter on 4 Nov 2019 for flea/tick control. Duke was in good overall health prior to product administration. A few hours after receiving FL a serous discharge appeared at the application site. On the following days anorexia started to be experienced and the dog became lethargic. On 5 Nov 2019* the discharge became serosanguineous, so, Duke was taken to the vet clinic. A trichotomy was performed around the lesion and were found a sore with purulent discharge, blood. Fever, local pain and agitation were also detected on physical examination. Asepsis was performed in the lesion, antibiotic and topical products were provided for treatment and Rifocina® Spray was prescribed for use at home. Duke remains 'debilitated' - he is still lethargic and anorexia and local pain are ongoing. According to the reporter, the DVM's diagnosis was moist dermatitis caused by FL. There is no history of AEs to other products in the past. The veterinarian informed to the pet owner that same issue occurred to other dogs, so, another SAE case was created on BRA-BIAHPV1P-19BR005276. Three pictures of the application site lesion were received. No further information is available.
06-Nov-2019	UAE; 19BR005276; DF; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	Aug-2019*	Aug-2019*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the veterinarian via a person not related to the patients of this case, an unknown number of dogs of unknown signalment received FRONTLINE (FL) (unsubstantiated; topical use; lot, exp dateand location are not known) administered by unknown person on Aug 2019* for unknown reason. The dogs experienced allergy and lesion at the application site an unknown time after product administration. Their current health status is not known. Similar SAE case involving another dog was created on BRA-BIAHPV1P-19BR005275. This is the extent of the information available.
08-Nov-2019	UAE; 19BR005280; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M	1	1	0	**Product used:** FIPRONIL SPRAY **Other products**	23-Sep-2019	23-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nicos, a male crossbred cat of 4 years old and 6 kg, was treated with FRONTLINE SPRAY (FL) (002/18B, unknown exp date, topical, parts of the body), applied by the reporter 45 days ago (23

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ED_005739D_00014391-00064

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** 4.00 Year(s) **Weight:** 6 kg				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					Sep 2019), for flea treatment. However, the pet remains with fleas. Environment treated with Butox®. FL has been applied every 45 days since date not specified. There is one more cat in this household that was treated with FL and it has the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005281). The owner also complained that she applied FRONTLINE 'pipette' and the product was not effective (SLOE case reported on BRA-BIAHPV1P-19BR005282). No further information is expected.
08-Nov-2019	UAE; 19BR005281; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Sep-2019	23-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Gigi, a female crossbred cat of 13 years old and 6 kg, was treated with FRONTLINE SPRAY (FL) (002/18B, unknown exp date, topical, whole body), applied by the reporter 45 days ago (23 Sep 2019), for flea treatment. However, the pet remains with fleas. Environment treated with Butox®. FL has been applied every 45 days since date not specified. There is one more cat in this household that was treated with FL (parts of the body/low dose) and it has the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005280). The owner also complained that she applied FRONTLINE 'pipette' and the product was not effective (SLOE case reported on BRA-BIAHPV1P-19BR005282). No further information is expected.
08-Nov-2019	UAE; 19BR005282; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 6 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2018*	2018*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two crossbred cats (Nicos, male, 4 years old and 6 kg; Gigi, female, 13 years old and 6 kg), were treated with one vial of FRONTLINE PIPETTE (unsubstantiated) (lot, exp date, route and location are unknown), applied to each cat by the reporter on date not informed (2018*) for flea treatment. However, the product was not effective. The owner also complained that she applied FRONTLINE SPRAY on her cats and they remain with fleas (SLOE cases reported on BRA-BIAHPV1P-19BR005280 and BRA-BIAHPV1P-19BR005281). No further information is expected.
07-Nov-2019	UAE; 19BR005284; RJ; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** X **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 3.4 - 4 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Oct-2019	07-Nov-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 Shih Tzus of 2 years old (Tosk, male, 4 kg; Bela, female, 3.4 kg) were treated with FRONTLINE SPRAY 250 ML (FL) (lots and exp dates are unknown, topical, whole body) administered by the reporter a month ago (7 Oct 2019) for tick treatment. Lack of efficacy is suspected because live ticks returned to be found on the dogs one month after receiving the product. FL has been administered every 4 months with no issue (1st adm date not provided). Environment treated with K-Othrine® and Butox®. There are 2 other dogs of the same household that also received FL and LOE is suspected (BRA-BIAHPV1P-19BR005285). No further information is available.
07-Nov-2019	UAE; 19BR005285; RJ; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products	07-Oct-2019	07-Nov-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 dogs of 7 weeks old were treated with FRONTLINE SPRAY 250 ML (FL) (lot and exp date are unknown, topical, whole body) administered by the reporter a month ago (7 Oct 2019) for tick treatment. Lack of efficacy is suspected because live ticks returned to be found one month after receiving the product. It is unknown if

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ED_005739D_00014391-00065

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 7.00 Week(s) **Weight:** Unknown				**Route:** Topical / Cutaneous **Was the product used ok?:** Yes					FL has been administered in the past. Environment treated with K-Othrine® and Butox®. There are 2 other dogs of the same household that also received FL and LOE is suspected (BRA-BIAHPV1P-19BR005284). No further information is available.
08-Nov-2019	UAE; 19BR005290; MG; Brazil	**Species:** Canine **Breed:** Pug **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 7 - 9 kg	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Oct-2019	23-Oct-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 dogs of unknown signalment, received one pipette of FRONTLINE (unsubstantiated) (FL) (lot and exp. date unknown; topical, btw the shoulder blades) each, applied by the reporter on 16 Oct 2019* for flea and tick treatment. Lack of efficacy is suspected because the dogs remain with fleas and ticks. Environmental factors are not known. This is the extent of the information available. UPDATE 12 NOV 2019 - The owner was contacted and reported that her two Pugs (Thor, male, 4 years old and 9 kg; Nina, female, 1 year old and 7 kg) were treated with one vial of FRONTLINE SPOT-ON DOG S (FRONTLINE) (topical, btw the shoulder blades), applied to each dog by the reporter on 23 Oct 2019, for tick treatment. It is unknown if the dogs remain with ticks. Flea infestation was not mentioned by the reporter during this update. Environment not treated. FRONTLINE was applied for the first time around Mar 2019*. No further information is expected.
10-Nov-2019	UAE; 19BR005296; CE; Brazil	**Species:** Canine **Breed:** Doberman **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 34 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	20-Oct-2019	20-Oct-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Thor, a male Doberman of 34 kg and 10 years old, received one pipette of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp. date unknown; topical, btw the shoulder blades), applied by the reporter on 20 Oct 2019 for flea and tick control. Lack of efficacy is suspected because ticks were found on the dog and on the environment. On 1 Nov 2019* the dog received FL once again and ticks continued to be found, so on 10 Nov 2019 Effipro Spray® was administered for treatment and the animal is currently ectoparasite free. FL has been administered for 2 years (dose frequency and first administration date not provided) with no issue. Environment not treated. No further information is available.
11-Nov-2019	UAE; 19BR005298; SP; Brazil	**Species:** Feline **Breed:** Feline various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 4 - 5 kg	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Nov-2019	06-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two cats (Floyd, male, unknown breed, 7 years old an 5 kg; Tina, female, Siamese, 14.5 years old and 4 kg) received one vial of FRONTLINE SPOT-ON CAT (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, applied to each cat by the reporter on 6 Nov 2019, for flea treatment. However, the pet remains with fleas. Environment treated with Butox®. No further information is expected.
08-Nov-2019	UAE; 19BR005301; RJ; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products	01-Nov-2019	01-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female cat of unknown signalment, received FRONTLINE PLUS CATS (FL) (lot and exp. date unknown; topical, administration site unknown), applied by the reporter on 1 Nov 2019 for lice treatment. Lack of efficacy is suspected because lice are still being found on the cat. Environmental factors are not known. This is the extent of the information available for now.

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ED_005739D_00014391-00066

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** Unknown to Company					
09-Nov-2019	UAE; 19BR005304; SE; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2019*	2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment received FRONTLINE PLUS (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 2019*. However, the product was not effective (details were not provided). FL was applied in the past (dose frequency is unknown and first application was not informed). This is the extent of the information available.
11-Nov-2019	UAE; 19BR005309; RJ; Brazil	**Species:** Canine **Breed:** American Bully **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 5.5 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	27-Oct-2019	27-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Maya, a female American Bully of 2 months old and 5.5 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (006/19A, unknown exp date, topical, parts of the body - low dose), applied by the reporter 15 days ago (27 Oct 2019), for tick treatment. However, the pet remains with ticks. Environment not treated. No further information is expected.
10-Nov-2019	UAE; 19BR005314; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	30-Oct-2019*	10-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a female cat of unknown signalment, received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp. date, route, administration site are unknown), applied by the reporter on 30 Oct 2019* for flea treatment. Lack of efficacy is suspected because the owner returned to see fleas on her cat. In addition, the pet is scratching itself due to fleas and because of that it is presenting wounds. The pet has no outdoor access. Environment treated with K-Othrine®. This is the extent of the information available for now.
12-Nov-2019	UAE; 19BR005315; -; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 30.00 Month(s)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	Aug-2019*	Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, Fred, a male Yorkshire of 30 months old and 5 kg*, received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter around 3 months ago (Aug 2019*), for flea treatment. However, fleas were found on her pet. The current status of the animal is unknown. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). Environment

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ED_005739D_00014391-00067

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 5 kg				**Route:** unknown **Was the product used ok?:** Unknown to Company					not treated. There are stray cats that have access to this household. No further information is expected.
12-Nov-2019	UAE; 19BR005318; RJ; Brazil	**Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 40 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Nov-2019	02-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pity, a female Pit Bull of 7 months old and 40 kg, received one pipette of FRONTLINE PLUS DOG XL (FL) (008/18B, exp date unknown; topical, btw the shoulder blades), administered orally by the reporter on 2 Nov 2019 for tick treatment. Lack of efficacy is suspected because ticks are still being seen on Pity. FL has been administered approximately every 3 months (first administration date not provided) with no issue. Pity is bathed every 4 days. Environment treated with Butox® every 2 days. No further information is available.
12-Nov-2019	UAE; 19BR005319; RS; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Oct-2019	20-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Luna, a female crossbred cat of 8 months old and 3 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date unknown; topical, btw the shoulder blades) for the first time, administered orally by the reporter on 20 Oct 2019 for flea treatment. Lack of efficacy is suspected because fleas are still being seen on Luna. Environment not treated. No further information is available.
12-Nov-2019	UAE; 19BR005323; RS; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	11	11	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Sep-2019*	Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 11 dogs of various breeds received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter 2 months ago (Sep 2019*), for flea treatment. However, the animals remained with fleas. So, 15 days post product application (Oct 2019*), Ectopar® was administered and the animals are currently free of fleas. Environment treated with amitraz. There is one more dog in this household that was treated with FRONTLINE PLUS DOG S and it had the same issue (SLOE case reported on BRA-BIAHPV1P-19BR004994). The owner also complained that she applied FRONTLINE (unsubstantiated) in the past and the product was not effective (SLOE case reported on BRA-BIAHPV1P-19BR005324). No further information is expected.
12-Nov-2019	UAE; 19BR005324; RS; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used**	2017*	2017*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown number of dogs received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter around 2 years ago (2017*). However, the product was not effective (details were not provided). Environmental factors are unknown. The owner mentioned that she she decided to apply FRONTLINE PLUS DOG S this year (2019*) and her dog remained with fleas (SLOE case reported on BRA-BIAHPV1P-19BR004994). She also applied FRONTLINE (unsubstantiated) on 11 dogs and they also remained with fleas (SLOE case reported on BRA-BIAHPV1P-19BR005323). No

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ED_005739D_00014391-00068

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					further information is expected.
11-Nov-2019	UAE; 19BR005325; RS; Brazil	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 6.8 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Oct-2019	10-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Falcão, a male German Shepherd of 2 months old and 6.8 kg, received FRONTLINE SPRAY 100 ML (FL) (002/19, exp date is unknown, topical, whole body) for the first time, administered by the reporter on 10 Oct 2019 for flea treatment. The dog was experiencing diarrhea prior to FL use and, according to the reporter, the veterinarian attributed the sign to the flea infestation. Falcão has history of persistent diarrhea caused by unknown reason which, at the time, stopped after an unknown treatment was provided. After receiving FL on 10 Oct 2019 Falcão started to run and experienced intense itching and urticarial rash. He was taken to the vet clinic but no treatment was provided. He recovered on an unspecified date (17 Oct 2019*). According to the reporter, the vet recommended that FL was applied once again and on 30 Oct 2019* the product was administered but same issue occurred (see case BRA-BIAHPV1P-19BR005326). No further information is available.
11-Nov-2019	UAE; 19BR005326; RS; Brazil	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 6.8 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	30-Oct-2019*	30-Oct-2019*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Falcão, a male German Shepherd of 2 months old and 6.8 kg, received FRONTLINE SPRAY 100 ML (FL) (002/19, exp date is unknown, topical, whole body) administered by the reporter on 30 Oct 2019* for flea treatment. The dog was experiencing diarrhea prior to FL use and, according to the reporter, the veterinarian attributed the sign to the flea infestation. Falcão has history of persistent diarrhea caused by unknown reason which, at the time, stopped after an unknown treatment was provided. After receiving FL on 30 Oct 2019* Falcão started to run and experienced intense itching and small lumps on his skin. He was taken to the vet clinic on 7 Nov 2019 but no treatment was provided. Same issue occurred on 10 Oct 2019 (see case BRA-BIAHPV1P-19BR005325). No further information is available.
12-Nov-2019	UAE; 19BR005333; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 12.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Intentional)	10-Nov-2019	11-Nov-2019	1 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Mel, a female crossbred dog of 6 years old and 12.5*, received one pipette of FRONTLINE PLUS DOGS M (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 10 Nov 2019 for itching treatment. There is confousing information regarding if fleas were visualized prior FL use , however, fleas or ticks are not being found. Although Mel was mildly scratching herself prior to FL, shel was in good overall health. On 11 Nov 2019 the itching became more intense and skin erythema on some locations of the body is also being experienced (the owner relates this one to the scratches). Mel was not taken to the veterinarian and no treatment has been provided. FL has been administered in the past (dose frequency and 1st adm date not provided) with no issue. There is no history of AEs to other products in the past. No further information is available.
12-Nov-2019	UAE; 19BR005342; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown	5	5	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products**	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 5 cats of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the reporter on date not provided (1 Nov 2019 – chosen at random) for unknown reason. According to the reporter, the product was not effective.

N/A signifies the information for this field is either not available or not applicable

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* indicates Approximate date or weight.

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ED_005739D_00014391-00069

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - **Weight:** Unknown				**used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					The current status of the animals is unknown. Environmental factors are not known. This is the extent of the information available for now.
12-Nov-2019	UAE; 19BR005345; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 2 - 9 kg	7	7	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	31-Oct-2019	31-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 7 mixed crossbred cats from 2 to 9 kg and from 1 to 16 years old*, received one pipette of FRONTLINE PLUS CATS (FL) (007/18A, exp date is unknown, topical, btw the shoulder blades) each, administered by the reporter on 31 Oct 2019 for flea treatment. Lack of efficacy is suspected because the pets remain with fleas . FL has been administered in the past (dose frequency and 1st adm date not provided) with no issue. There are 2 untreated dogs living in the same household. Environment not treated. No further information is available.
31-Oct-2019	UAE; 19BR005347; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 2.5 - 3.5 kg	4	4	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Oct-2019	05-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 crossbred cats of mixed sex, from 1 year old to 4 years old, 2.5 kg to 3.5 kg, were treated with one vial of FRONTLINE SPOT-ON CAT (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied, to each cat, by the reporter on 5 Oct 2019, for flea treatment. However, the animals remain with fleas. Environment treated with Butox®. FL has been applied every 5 months with no issue since date not specified. The are 2 more cats in this household that were treated with FRONTLINE PLUS CATS and they have the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005348). No further information is expected.
31-Oct-2019	UAE; 19BR005348; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 2.8 - 3.5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Oct-2019	05-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 crossbred cats of mixed sex (Milena, female, 3 years old and 3.5 kg; Sansão, male 1 year old and 2.8 kg), were treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied, to each cat, by the reporter on 5 Oct 2019, for flea treatment. However, the animals remain with fleas. Environment treated with Butox®. FL has been applied every 5 months since date not specified. The are 2 more cats in this household that were treated with FRONTLINE SPOT-ON CATS and they have the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005347). No further information is expected.
13-Nov-2019	UAE; 19BR005350; RJ; Brazil	**Species:** Canine **Breed:** French Bulldog **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Month(s) **Weight:** 7 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	02-Nov-2019	12-Nov-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female French Bulldog of 14 months old and 7 kg*, received, for the first time, one vial of FRONTLINE PLUS DOG S (022/18A, unknown exp date, topical, btw the shoulder blades), applied by the reporter on 2 Nov 2019, for tick prevention. 10 days post product application, ticks have been found on his pet. Environment treated with an unknown product. No further information is expected.

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ED_005739D_00014391-00070

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					
12-Nov-2019	UAE; 19BR005353; PR; Brazil	**Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 3.8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Oct-2019	12-Nov-2019	3 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a female dog of other signalment unknown, received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the reporter on 22 Oct 2019 for flea control. Lack of efficacy is suspected because on 12 Nov 2019 one flea was found on the dog, in addition it has flea allergy dermatitis. The current status of the animal is unknown. Environmental factors are not known. This is the extent of the information available for now. UPDATE 21 NOV 2019 – The owner was contacted and reported that, Chanel, a female Lhasa Apso of 4 years old and 3.8 kg, received one pipette of FRONTLINE PLUS DOG S (topical, btw the shoulder blades). It is unknown if fleas are still being found on Chanel. Environment has not been treated.
13-Nov-2019	UAE; 19BR005356; RJ; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 14 kg	4	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	23-Oct-2019	30-Oct-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Jana, a female medium crossbred dog of 12 years old and 14 kg, received one vial of FRONTLINE PLUS DOG M (lot and exp date are unknown, topical, back - unknown location), applied by the reporter 3 weeks ago (23 Oct 2019), for tick control. Some days post product application, one live tick was found on his dog. The tick was manually removed and the pet is currently free of ectoparasites. Environment not treated. FL has been applied every 40 days since date not specified. There are 3 more dogs in this household that were treated with FRONTLINE PLUS (unsubstantiated) and they have no issue. Also, there are stray cats and wild animals that have access to the backyard. The owner also mentioned that some years ago he applied FRONTLINE (unsubstantiated) on his other dog and it was diagnosed with tick-borne disease (SLOE case reported on BRA-BIAHPV1P-19BR005357). No further information is expected.
13-Nov-2019	UAE; 19BR005357; RJ; Brazil	**Species:** Canine **Breed:** Beagle **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2007*	2007*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Leo, a male Beagle (other signalment is unknown), received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 2007*. 10 days post product application, the pet started limping. He was taken to the vet and diagnosed with tick-borne disease. There is no information regarding the current status of this animal. Now, the owner also mentioned that he applied FRONTLINE PLUS DOG M on his other dog and one tick was found (SLOE case reported on BRA-BIAHPV1P-19BR005356). This is the extent of the information available.
13-Nov-2019	UAE; 19BR005364; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 16 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	08-Nov-2019	08-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Belinha, a female medium crossbred dog of 6 years old and 16 kg, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 8 Nov 2019, for flea treatment. However, the pet remains with fleas. Environment not treated. FRONTLINE was applied in the past (dose frequency is unknown and first application was not provided). No further information is expected.

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ED_005739D_00014391-00071

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					
12-Nov-2019	UAE; 19BR005365; ES; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 1.5 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	06-Oct-2019	06-Oct-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a cat of unknown signalment, received FRONTLINE SPRAY (FL) (lot, exp. date, route and administration site are unknown), administered by the reporter on Sep 2019* for flea treatment. Lack of efficacy is suspected because the cat remains with fleas, in addition is scratching itself due to the fleas. Environmental factors are not known. This is the extent of the information available for now. UPDATE 14 NOV 2019 - The owner was contacted and reported that Aquira , a male crossbred cat of 3 months old and 1.5 kg was treated with FRONTLINE SPRAY (002/19A, unknown exp date, topical, whole body), applied by the reporter on 6 Oct 2019, 20 Oct 2019* and 5 Nov 2019, for flea treatment. However, the pet remains with fleas. Environment not treated. No further information is expected.
13-Nov-2019	UAE; 19BR005369; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 13 kg	3	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Oct-2019*	05-Nov-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bela, a female medium crossbred dog of 12 years old and 13 kg, received FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter 2 weeks ago* (30 Oct 2019*), for flea/tick control. However, her pet got ectoparasites. Environment treated with Butox®. FL has been applied every 3 months with no issue for the past 12 years. There are two more dogs in this household that were treated with FL and they have no issue. No further information is expected.
14-Nov-2019	UAE; 19BR005374; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a cat of unknown signalment, received FRONTLINE PLUS CATS (FL) (lot, exp. date, route and administration site are unknown), administered by the reporter on date not specified (1 Nov 2019 – chosen at random) for flea/tick control. Lack of efficacy is suspected because the cat got fleas. Another product was administered on date not informed and no more fleas were reported. FRONTLINE was administered in the past (dose frequency and first administration date not provided) with no issue. Environmental factors are not known. There are other 2 dogs of the same household treated with FRONTLINE facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005375 and BRA-BIAHPV1P-19BR005376). This is the extent of the information available for now.
14-Nov-2019	UAE; 19BR005375; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a dog of unknown signalment, received FRONTLINE PLUS DOG S (FL) (lot, exp. date, route and administration site are unknown), administered by the reporter on date not specified (1 Nov 2019 – chosen at random) for flea/tick control. Lack of efficacy is suspected because the dog got fleas. Another product was administered on date not informed and no more fleas were reported. FRONTLINE was administered in the past (dose frequency and first administration date not provided) with no issue. Environmental factors are not known. There are other 2 dogs of the same household treated with FRONTLINE facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005374 and

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ED_005739D_00014391-00072

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					BRA-BIAHPV1P-19BR005376). This is the extent of the information available.
14-Nov-2019	UAE; 19BR005376; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a dog of unknown signalment, received FRONTLINE PLUS DOG M (FL) (lot, exp. date, route and administration site are unknown), administered by the reporter on date not specified (1 Nov 2019 – chosen at random) for flea/tick control. Lack of efficacy is suspected because the dog got fleas. Another product was administered on date not informed and no more fleas were reported. FRONTLINE was administered in the past (dose frequency and first administration date not provided) with no issue. Environmental factors are not known. There are other 2 dogs of the same household treated with FRONTLINE facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005374 and BRA-BIAHPV1P-19BR005375). This is the extent of the information available for now.
13-Nov-2019	UAE; 19BR005385; BA; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 4.2 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	May-2019	May-2019	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Snoopy, a male Shih Tzu of 1 year old and 4.2 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, base of skull to btw the shoulder blades) for the first time, administered by the reporter on May 2019 for flea/tick treatment. Snoopy was in good overall health prior to FL application. One day after FL use, Snoopy's skin became darkened at the application site. The sign is still ongoing. In the following days the darkened areas became burn-like sores. The dog was taken to the veterinarian but no treatment was provided. According to the reporter, the DVM's level of suspicion is high. There is another dog in the same household but it was not treated with FL. LOE is suspected because fleas and ticks continued to be found on Snoopy during FL window of effectiveness (see BRA-BIAHPV1P-19BR005386). No further information is available.
13-Nov-2019	UAE; 19BR005386; BA; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 4.2 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	May-2019*	May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Snoopy, a male Shih Tzu of 1 year old and 4.2 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, base of skull to btw the shoulder blades) for the first time, administered by the reporter on May 2019 for flea/tick treatment. Lack of efficacy is suspected because fleas and ticks continued to be found for 3 months after treatment. NEXGARD® was administered on Aug 2019* and the animal is no longer presenting ectoparasites. There is another dog in the same household but it was not treated with FL. An adverse reaction involving the same product and patient was experienced (see case BRA-BIAHPV1P-19BR005385). Environment treated with Butox®. No further information is available.
14-Nov-2019	UAE; 19BR005393; SP; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Month(s) **Weight:** 2.35 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	20-Oct-2019	20-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Xulyana, a female neutered cat of 5 months old and 2.35 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, administered by the reporter on 20 Oct 2019 for flea treatment. Lack of efficacy is suspected because the cat is infested with fleas; in addition, fleas are being seen on the environment. Environment treated with Butox®. No further information is available.

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ED_005739D_00014391-00073

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					
14-Nov-2019	UAE; 19BR005394; MG; Brazil	**Species:** Canine **Breed:** Border Collie **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Month(s) **Weight:** 13 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** AFOXOLANER 68 MG CHEWABLE TABLETS; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	09-Nov-2019	01-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Perola, a female Border Collie of 5 months old and 13 kg, received NEXGARD (unsubstantiated) (NG) (lot and exp. date unknown), administered orally by the reporter on date not specified (1 Oct 19 – chosen at random) for flea and tick treatment. According to the reporter, fleas and ticks continued to be seen on the animal. Due to this, Perola received one pipette of FRONTLINE SPOT-ON DOG M (FL) (lot and exp. date unknown; topical, back - unspecified location) for the first time, on 9 Nov 2019 and it was not effective either. Environment treated with unknown product. No further information is available.
14-Nov-2019	UAE; 19BR005398; -; Brazil	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 25 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Oct-2019	15-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bianca, a female crossbred dog of 25 kg and unknown age, received one pipette of FRONTLINE PLUS DOGS L (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 15 Oct 2019 for unknown reason. Lack of efficacy is suspected because live ticks have been found on the dog. FL has been administered in the past (dose frequency and 1st adm date not provided; last adm date on Feb 2019) with no issue. Bianca is usually bathed once a week. Environment treated with Butox® on 5 Oct 2019 (it is unknown if it was treated again after this date). There are 5 other dogs of the same household that also received FRONTLINE and LOE is suspected (BRA-BIAHPV1P-19BR005399). No further information is available.
14-Nov-2019	UAE; 19BR005399; -; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** 12 - 20 kg	5	5	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Oct-2019	03-Nov-2019*	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 5 mixed crossbred dogs from 12 to 20 kg and unknown age, received one pipette of FRONTLINE PLUS DOGS M (lot and exp date are unknown, topical, btw the shoulder blades) each, administered by the reporter on 15 Oct 2019 for unknown reason. Lack of efficacy is suspected because live ticks have been found on the dogs. FL has been administered in the past (dose frequency and 1st adm date not provided; last adm date on Feb 2019) with no issue. The dogs are usually bathed once a week. Environment treated with Butox® on 5 Oct 2019 (it is unknown if it was treated again after this date). There is another dog of the same household that also received FRONTLINE and LOE is suspected (BRA-BIAHPV1P-19BR005398). No further information is available.
14-Nov-2019	UAE; 19BR005413; -; Brazil	**Species:** Canine **Breed:** Pomeranian **Sex:** M **Sex qualifier:** Unknown **Age:** 1.20 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	06-Nov-2019	06-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Robinho, a male Pomeranian of 1.2 years old and 3 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknown; topical, btw the shoulder blades), administered by the reporter on 6 Nov 2019 for flea treatment. Lack of efficacy is suspected because Robinho remains scratching himself and the reporter believes in the persistence of fleas, although no more fleas were reported. FL was administered in the past (dose frequency and first administration date not provided) with no issue.

N/A signifies the information for this field is either not available or not applicable

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ED_005739D_00014391-00074

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** Yes					Environment treated with Raid®. There is another dog of the same household treated with FRONTLINE and facing the same issue (see SLOE case reported on BRA-BIAHPV1P-19BR005414). No further information is available.
14-Nov-2019	UAE; 19BR005414; -; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 13 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Nov-2019	06-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Menina, a female crossbred dog of approx. 10 years old and 13 kg, received one pipette of FRONTLINE PLUS DOG M (FL) (lot and exp. date unknown; topical, btw the shoulder blades), administered by the reporter on 6 Nov 2019 for flea treatment. Lack of efficacy is suspected because Menina remains scratching herself and the reporter believes in the persistence of fleas, although no more fleas were reported. FL was administered in the past (dose frequency and first administration date not provided) with no issue. Environment treated with Raid®. There is another dog of the same household treated with FRONTLINE and facing the same issue (see SLOE case reported on BRA-BIAHPV1P-19BR005413). No further information is available.
15-Nov-2019	UAE; 19BR005421; RS; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 7.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Oct-2019	30-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lola, a female small crossbred dog of 7.5 kg and 5 years old*, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 30 Oct 2019, for flea treatment. However, the number of fleas has increased. Environment treated with Jimo®. FL was applied in the past (dose frequency is unknown and first application was not provided). No further information is expected.
18-Nov-2019	UAE; 19BR005422; SP; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 6.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Species not indicated / recommended)	28-Sep-2019	23-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a male cat of 7 years old and approx. 6.5 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot, exp date, route and location are not known) administered by the reporter on 28 Sep 2019 for flea/tick control. Lack of efficacy is suspected because fleas are being found on the cat since 23 Oct 2019* and it remains scratching itself due to the ectoparasite infestation. Another administration of FL was made on 7 Nov 2019* and the pet remains with fleas. According to the reporter, the cat usually spends time on a farm and he is bathed once a week. FL has been administered in the past (dose frequency and 1st adm date not provided) with no issue. Indoor environment treated with Butox® and steam cleaner. There are 2 dogs of the same household that have been simultaneously treated with FL and LOE is also suspected (BRA-BIAHPV1P-19BR005423). No further information is available.
18-Nov-2019	UAE; 19BR005423; SP; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** 6.5 kg*	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown	28-Sep-2019	23-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 mixed dogs of 6.5 kg received one pipette of FRONTLINE PLUS DOGS S (FL) (lot, exp date, route and location are not known) each, administered by the reporter on 28 Sep 2019 for flea/tick control. Lack of efficacy is suspected because fleas are being found on the dogs since 23 Oct 2019* and they remain scratching themselves due to the ectoparasite infestation. Another administration of FL was made on 7 Nov 2019* and the pet remains with fleas. According to the reporter, the dogs usually

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ED_005739D_00014391-00075

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					spend time on a farm and they are bathed once a week. FL has been administered in the past (dose frequency and 1st adm date not provided) with no issue. Indoor environment treated with Butox® and steam cleaner. There is 1 cat of the same household that has been simultaneously treated with FL and LOE is also suspected (BRA-BIAHPV1P-19BR005422). No further information is available.
18-Nov-2019	UAE; 19BR005430; SP; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 4.8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	29-Oct-2019*	13-Nov-2019*	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Noah, a male Yorkshire of 11 years old and 4.8 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (022/18A, unknown exp date, topical, unknown location), applied by the reporter on 29 Oct 2019*, for flea control. However, the pet got fleas approximately 15 days after treatment. Environment treated with Butox®. FL has been applied every 2 months with no issue since date not specified. No further information is expected.
16-Nov-2019	UAE; 19BR005433; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-A	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a dog of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the reporter on date not provided (Nov 2019* – chosen at random) for flea treatment. According to the reporter, the dog received the product while it was hospitalized and, one day after the application, the DVM informed that FL was not effective. The current status of the animal is unknown. The reporter also mentioned that there is another dog that was treated with FL and experienced the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005434). This is the extent of the information available for now. UPDATE 21 NOV 2019 – The pet owner was contacted and informed that the animal received Comfortis® as treatment and the issue was solved. The dog was euthanized due to other cause that was not related to the product admnistration. No further information is expected.
16-Nov-2019	UAE; 19BR005434; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2017*	2017*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a dog of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the reporter on date not provided (2017* – chosen at random) for unknown reason. According to the reporter, the product was not effective and an unknown product was purchased as treatment; however, it is unknown if the issue was solved. Environmental factors are not know. The reporter also mentioned that there is another dog that was treated with FL and experienced the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005433). This is the extent of the information available for now.
17-Nov-2019	UAE; 19BR005437; SP; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	10-Nov-2019*	17-Nov-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, one dog of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 10 Nov 2019*. However, on 17 Nov

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ED_005739D_00014391-00076

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** 12.00 Year(s) **Weight:** 7.5 kg				9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					2019, the owner complained that the product was not effective agains fleas. This is the extent of the information available. UPDATE 22 NOV 2019 - The owner was contacted and reported that Tiffany, a female Shih Tzu of 12 years old and 7.5 kg, was treated with one vial of FRONTLINE PLUS DOG S (topical, btw the shoulder blades), for flea control. However, on 17 Nov 2019, the owner saw some fleas on her pet, who was bathed and the owner manually removed all the fleas. Now, the pet is free of ectoparasites. Environment not treated. FL was applied 10 years ago with no issue. No further information is expected.
16-Nov-2019	UAE; 19BR005438; SC; Brazil	**Species:** Canine **Breed:** Siberian Husky **Sex:** M **Sex qualifier:** Unknown **Age:** 11.00 Month(s) **Weight:** 20 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	14-Nov-2019	16-Nov-2019	2 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, a dog of unknown signalment received FRONTLINE PLUS (FL) (unsubstantiated; topical route; lot, exp date and location are not known) administered by the reporter on 14 Nov 2019 for flea/tick control. Two days post FL application (16 Nov 2019) the pet owner noted a skin lesion with discharge and 'tiny holes' at the application site. The signs are ongoing and the pet was not taken to the veterinarian yet. There are an unknown number of dogs of the same household but it was not informed if they also received FL. This is the extent of the information available for now. UPDATE 19 Nov 2019 – The pet owner was contacted and reported that Panda, a male Siberian Husky of 11 months old and 20 kg received FL for the first time on 14 Nov 2019 and on 16 Nov 2019 was noted that his skin was dry and reddened at the application site. The vet was contacted but the animal was not examined by him. According to the reporter, the vet informed that Panda experienced an 'allergy'. He is currently under treatment with topical ointment (Ganadol®) and antiseptic product; it is unknown if he fully recovered but the owner informed that his condition improved. The was in good overall health prior to product administration and there is no history of AEs to other products in the past. No further information is available.
18-Nov-2019	UAE; 19BR005443; SP; Brazil	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 20.1 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	23-Oct-2019	23-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Negão, a male large crossbred dog of 20.1 kg and unknown age, was treated with three vials of FRONTLINE SPOT-ON DOGS S (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 23 Oct 2019, for tick treatment. However, the pet remained with ticks. So, she applied one vial of FRONTLINE PLUS DOG M (lot and exp date are unknown, topical, btw the shoulder blades, low dose), applied on 10 Nov 2019. However, the pet remains with ticks. Environment treated with Butox®. FRONTLINE (unsubstantiated) was applied 6 months ago. There is one more dog in this household that was not treated with FRONTLINE and it has no issue. is the extent of the information available.
18-Nov-2019	UAE; 19BR005448; SP; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	15-Jul-2019*	15-Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Preta, a female crossbred dog of 17 years old and 15 kg, received one pipette of FRONTLINE (unsubstantiated) (FL) (lot and exp. date unknown; topical, application site unknown), administered by the reporter on 15 Jul 2019* for flea treatment. According to the reporter the product was not effective because the dog remained

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ED_005739D_00014391-00077

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 17.00 Year(s) **Weight:** 15 kg				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					with fleas. On 15 Sep 2019* NEXGARD was administered as treatment and the issue was solved. FL has been usually administered every 3 months or so since 2009* with no issue.There is another dog of the same household that uses a collar for ectoparasite control. On 14 No 2019, another dose was administered and also was ineffective (SLOE case reported on BRA-BIAHPV1P-19BR005449). Environment treated with Butox®. No further information is available.
18-Nov-2019	UAE; 19BR005449; SP; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 17.00 Year(s) **Weight:** 15 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	15-Nov-2019	15-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Preta, a female crossbred dog of 17 years old and 15 kg, received one pipette of FRONTLINE PLUS DOG M (FL) (005/18A, exp. date unknown; topical, btw the shoulder blades and tail), administered by the reporter on 14 Nov 2019 for flea treatment. According to the reporter the product was not effective because the dog remains with fleas. FL has been usually administered every 3 months or so since 2009 and LOE is also suspected for the previous administration made 4 months ago (see case reported on BRA-BIAHPV1P-19BR005448). There is a dog treated with an ectoparasiticide collar with no issue living in this house. Environment treated with Butox®. No further information is available. UPDATE 21 NOV 2019 – The pet owner was contacted and informed that FL was actually administered on 15 Nov 2019. An unknown product was administered as treatment; however the dog remains with fleas. According to the reporter, fleas are also being seen on the environment. No further information is expected.
18-Nov-2019	UAE; 19BR005454; PR; Brazil	**Species:** Canine **Breed:** Schnauzer **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 6 - 7 kg	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Oct-2019	29-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 Schnauzers; 1 male of 3 years old and 7 kg, 2 females from 1 to 3 years old and 6 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknown; topical, btw the shoulder blades), administered by the reporter on 29 Oct 2019 for flea treatment. According to the reporter the product was not effective because the dogs remained with fleas. Capstar® was administered as treatment but the pets remain with fleas. FL was administered in the past (dose frequency and first administration date not provided) with no issue. There are other 2 dogs of the same household treated with FRONTLINE facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005455). Environment treated with product not informed. No further information is available.
18-Nov-2019	UAE; 19BR005455; PR; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 10 - 18 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Oct-2019	29-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 male dogs (Buddy, crossbred, 3 years old, 18 kg; Schott, Yorkshire Terrier, 9 years old, 10 kg), received one pipette of FRONTLINE PLUS DOG M (FL) (lot and exp. date unknown; topical, btw the shoulder blades), administered by the reporter on 29 Oct 2019 for flea treatment. According to the reporter the product was not effective because the dogs remained with fleas. In addition, Schott has flea allergy dermatitis and had hair loss due to this. Capstar® was administered as treatment but the pets remain with fleas. FL was administered in the past (dose frequency and first administration date not provided) with no issue. There are other 3 dogs of the same household treated with FRONTLINE facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005454). Environment treated with product not informed. No further information is available.
19-Nov-2019	UAE; 19BR005459;	**Species:** Canine **Breed:** Small	1	1	0	**Product used:** FIPRONIL SPOT	19-Oct-2019	19-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lilica, a female crossbred dog of unknown age and 3 kg, received

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ED_005739D_00014391-00078

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	PR; Brazil	crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 3 kg				ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					one pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 19 Oct 2019 for flea/tick control. Lack of efficacy is suspected because fleas are being found on the dog. FL has been administered every 3 months with no issue (1st adm date not provided). Lilica is usually bathed once a week. Environment not treated. No further information is available.
19-Nov-2019	UAE; 19BR005461; MG; Brazil	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	20-Sep-2019	16-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a dog of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the reporter on 16 Sep 2019 for flea and tick treatment. According to the reporter the product was not effective because some live attached ticks remain to be seen on the dog. FL was administered on the pas (dose frequency and first administration date unknown) with no issue. Environmental factors are not known. This is the extent of the information available for now. UPDATE 21 NOV 2019 – The owner was contacted and reported that Luck, a male Maltese of 3 years old and 5 kg, received FRONTLINE SPOT-ON DOGS S (lot and exp. date unknown; topical, btw the shoulder blades), administered by the DVM on 20 Sep 2019 for tick treatment. The dog remains with ticks. FL has been administered every 3-6 months since 2016 with no issue. Environment has not been treated. No further information expected.
17-Nov-2019	UAE; 19BR005464; RJ; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** X **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 8 - 9.5 kg*	5	5	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Nov-2019	04-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 5 dogs of less than 10 kg were treated with one vial of FRONTLINE SPOT-ON DOGS S (lot, exp date, route and location are unknown), applied, to each dog, by the reporter on 4 Nov 2019, for tick treatment. However, the animals remain with ticks. There are other dogs in this household with the same issue (SLOE cases reported on BRA-BIAHPV1P-19BR005465 and BRA-BIAHPV1P-19BR005466). No further information is available. UPDATE 5 DEC 2019 - The owner was contacted and reported that her 5 dogs from 5 years old to 10 years, weighting from 8 kg to 9.5 kg and mixed sex, received, for the second time, one vial of FRONTLINE SPOT-ON DOGS S (FL) (topical, btw the shoulder blades), for flea/tick treatment. Fleas have died, however, the owner continued to see ticks on her dogs. So, she administered NEXGARD and it was effective. Environment not treated. FL was applied for the first time with no issue on date not specified. No further information is expected.
17-Nov-2019	UAE; 19BR005465; RJ; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 17 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Nov-2019	04-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 1 medium dog was treated with one vial of FRONTLINE SPOT-ON DOGS M (lot, exp date, route and location are unknown), applied by the reporter on 4 Nov 2019, for tick treatment. However, the animal remains with ticks. There are other dogs in this household with the same issue (SLOE cases reported on BRA-BIAHPV1P-19BR005464 and BRA-BIAHPV1P-19BR005466). No further information is available. UPDATE 5 DEC 2019 - The owner was contacted and reported that, Teca, a female medium crossbred dog of 6 years old and 17 kg, received, for the second time, one vial of FRONTLINE SPOT-ON DOGS M (FL) (topical, btw the shoulder blades), for flea/tick treatment. Fleas have died, however, the owner continued

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* indicates Approximate date or weight.

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ED_005739D_00014391-00079

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											to see ticks on her dogs. So, she administered NEXGARD and it was effective. Environment not treated. FL was applied for the first time with no issue on date not specified. No further information is expected.
17-Nov-2019	UAE; 19BR005466; RJ; Brazil	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 27 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Nov-2019	04-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 1 large dog was treated with one vial of FRONTLINE SPOT-ON DOGS L (lot, exp date, route and location are unknown), applied by the reporter on 4 Nov 2019, for tick treatment. However, the animals remain with ticks. There are other dogs in this household with the same issue (SLOE cases reported on BRA-BIAHPV1P-19BR005464 and BRA-BIAHPV1P-19BR005465). No further information is available. UPDATE 5 DEC 2019 - The owner was contacted and reported that, Tulio, a male large crossbred dog of 8 years old and 27 kg, received, for the second time, one vial of FRONTLINE SPOT-ON DOGS L (FL) (topical, btw the shoulder blades), for flea/tick treatment. Fleas have died, however, the owner continued to see ticks on her dogs. So, she administered NEXGARD and it was effective. Environment not treated. FL was applied for the first time with no issue on date not specified. No further information is expected.
19-Nov-2019	UAE; 19BR005471; SP; Brazil	**Species:** Canine **Breed:** Pit Bull **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 22 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL SPOT ON DOG; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Max, a male Pit Bull of 6 years old and 22 kg, received one pipette of FRONTLINE PLUS DOG L (FL) (032/18A, exp. date unknown; topical, btw the shoulder blades), administered by the reporter on Oct 2019* for tick treatment. According to the reporter the product was not effective and lack of efficacy is suspected because Max remained with ticks. On 1 Nov 2019, FRONTLINE SPOT-ON DOGS L (011/28A, exp. date unknown; topical, btw the shoulder blades) was administered and was also not effective , the pet remains with ticks. Environment treated with Butox®. No further information is available.
19-Nov-2019	UAE; 19BR005476; SP; Brazil	**Species:** Feline **Breed:** Persian (No Further Description) **Sex:** M **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** 3 kg	7	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Sep-2019*	03-Sep-2019*	1 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Frederico, a male intact Persian cat of 4 years old and 3 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 2 Sep 2019* for unknown reason. One day after FL use (3 Sep 2019*) intense itching at the application site started to be experienced by Frederico and he began pulling out his fur. On 4 Sep 2019* erythema, alopecia, increased skin temperature and a small sore were seen on the location. The application site was cleaned with water. The DVM was contacted by the pet owner but the animal was not taken the vet clinic. Dexamethasone (0.3 ml, SC, every 5 days), bath and a topical bethametasone ointment were prescribed for treatment. Erythema, alopecia and intense itching are the signs that are currently ongoing. The pet owner is still washing the application site with water and Frederico remains under treatment with the mentioned products. Same FL has been applied only once in the past (2017*) and the cat experienced similar issue (BRA-BIAHPV1P-19BR005477). There are 6 other cats of the same household that were also treated with FL but with no issue.The veterinarian informed BIAH that Frederico is a breeding cat and he suffers from stress due to the breeding

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* indicates Approximate date or weight.

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ED_005739D_00014391-00080

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											routine. She added that he and the 6 other cats of same household have chronic dermatopathies, including dermatophytosis, and the last time she examined Frederico (date not informed) he was skinny. Her level of suspicion is medium. No further information is available.
19-Nov-2019	UAE; 19BR005477; SP; Brazil	**Species:** Feline **Breed:** Persian (No Further Description) **Sex:** M **Sex qualifier:** - **Age:** 2.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	2017*	2017*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Frederico, a male Persian cat of 2 years old* and unknown weight, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 2017* for unknown reason. Moderate pruritus, erythema and alopecia at the application site were experienced by Frederico after FL use. He was taken to the veterinarian and an injection containing antiallergic medication was applied for treatment. The signs improved an unknown time later. Same FL has been applied once again, on 2 Sep 2019*, and the cat experienced similar issue (BRA-BIAHPV1P-19BR005476). This is the extent of the information available.
18-Nov-2019	UAE; 19BR005478; SE; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, two cats of unknown signalment received FRONTLINE PLUS CATS (lot, exp date, route and location are unknown), applied, to each cat, by the reporter on date not specified (Nov 2019*). for flea treatment. However, the product was not effective because the animals remain with fleas. This is the extent of the information available.
19-Nov-2019	UAE; 19BR005479; -; Brazil	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Nov-2019	19-Nov-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mayla, a female Jack Russel Terrier of 4 years old and 4 kg*, was treated, for the second time, with one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 16 Nov 2019, for flea treatment. However, on 19 Nov 2019, the owner saw one flea on Mayla's head. The current status of the animal is unknown. Environment not treated. FL was applied for the first time on date not specified. No further information is expected.
18-Nov-2019	UAE; 19BR005485; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	03-Nov-2019	03-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via retail store staff member, one dog of 8 kg (other signalment is unknown) was treated with FRONTLINE (unsubstantiated) (014/18A, exp date, route and location are unknown), applied by the reporter on 3 Nov 2019, for tick treatment. However, the pet remains with ticks. Environment treated with cypermethrin. This is the extent of the information available.

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ED_005739D_00014391-00081

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
18-Nov-2019	UAE; 19BR005487; RJ; Brazil	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 23 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	08-Nov-2019	08-Nov-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, one female dog of unknown signalment received FRONTLINE (unsubstantiated) (FL) (032/18B, Sep 2020, route and location are unknown), applied by the reporter on date not specified (Oct 2019*), for flea treatment. However, the pet continued with fleas. So, the owner applied another vial of FL (Nov 2019*) and it was not effective as well. Environment treated with an unknown product. This is the extent of the information available. UPDATE 28 NOV 2019 - The owner was contacted and reported that Dara, a female large crossbred dog of 10 years old and 23 kg, was treated with one vial of FRONTLINE PLUS DOG L (FRONTLINE) (032/18B, unknown exp date, topical, btw the shoulder blades), applied on 8 Nov 2019 and on 16 Nov 2019, for flea treatment. The number of fleas has decreased, however, the pet still has fleas. Environment treated with amitraz. FRONTLINE has been applied every 6 months with no issue since date not specified. No further information is expected.
19-Nov-2019	UAE; 19BR005497; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 14.00 Month(s) **Weight:** 19 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Nov-2019	04-Nov-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a dog of 19 kg and unknown signalment received FRONTLINE PLUS DOGS (FL) (unsubstantiated; lot, exp date, route and location are not known) administered by the reporter on Nov 2019* for flea treatment. Lack of efficacy is suspected because fleas are still being found on the dog. Environmental factors are not known. This is the extent of the information available for now. UPDATE 22 NOV 2019 - The owner was contacted and reported that Bob, a male medium crossbred dog of 14 months old* and 19 kg*, was treated, for the first time, with one vial of FRONTLINE PLUS DOG M (topical, btw the shoulder blades), applied by the reporter on 4 Nov 2019, for flea treatment. It is unknown if the animal remains with fleas. Environment treated with Butox®. The owner also mentioned that she had other dogs in the past and she applied FRONTLINE SPRAY on them, but the product was not effective (SLOE case reported on BRA-BIAHPV1P-19BR005573). No further information is expected.
20-Nov-2019	UAE; 19BR005498; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Nov-2019	30-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a female cat of unknown signalment received FRONTLINE (FL) (pipette presentation for cats – unsubstantiated; lot, exp date, route and location are not known) for the first time, administered by the reporter on 15 Nov 2019* for flea treatment. Lack of efficacy is suspected because on 20 Nov 2019 was noted that the animal continues with fleas. Environment treated with K-Othrine®. This is the extent of the information available for now. UPDATE 6 Dec 2019 – The pet owner was contacted and reported that Chu, a crossbred cat of 5 years old and 4 kg, received one pipette of FRONTLINE SPOT-ON CATS (FL) (topical, btw the shoulder blades) on 30 Nov 2019 and fleas are still being found. FL has been administered in the past (dose frequency and 1st adm date not provided) with no issue. The cat has no outdoor access. The reporter mentioned that many people have been complaining about the lack of effectiveness of FRONTLINE, however, no valid patient info was provided. No further information is available.
21-Nov-2019	UAE; 19BR005500; SP; Brazil	**Species:** Canine **Breed:** Terrier Breeds (500 Series)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	20-Sep-2019*	25-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Princesa, a female Brazilian Terrier of 1 year old and approx. 7 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknown; topical, btw the shoulder blades), administered

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ED_005739D_00014391-00082

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 7 kg				9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					by the reporter on 20 Sep 2019* for ectoparasite control. Lack of efficacy is suspected because some days after FL administration , the dog went out and after that a huge amount of fleas and tick were seen. Approximately 10 days after FL admnistration, Princesa was bathed with an unknown ectoparasiticide shampoo as treatment and the issue was solved. FL was used in the past with no issue (frequency and date of first adm not provided). Environment treated with Butox®. No further information is available.
20-Nov-2019	UAE; 19BR005503; -; Brazil	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 1.7 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Nov-2019	20-Nov-2019	1 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Meg, a female Chihuahua of 6 months old and 1.7 kg, received FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body) for the first time, administered by the reporter on 19 Nov 2019 for unknown reason. The dog was in good health prior to product administration. One day after FL application (20 Nov 2019) Meg experienced apathy, conjunctival hyperemia and difficulty in opening the eyes. She was not taken to the vet and recovered on 21 Nov 2019* after being treatedtopically with 0.9% saline solution. There is no history of AEs to other products in the past. No further information is available.
19-Nov-2019	UAE; 19BR005504; SP; Brazil	**Species:** Canine **Breed:** Lhasa Apso **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Nov-2019	17-Nov-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Ted, a male Lhasa Apso of 6 years old and 8 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 11 Nov 2019, for flea treatment. However, on 17 Nov 2019, the owner found 3 fleas on his dog and he still has fleas. Environment not treated. FRONTLINE has been applied every 3 months with no issue since date not specified. No further information is expected.
22-Nov-2019	UAE; 19BR005525; SP; Brazil	**Species:** Canine **Breed:** Pomeranian **Sex:** M **Sex qualifier:** Unknown **Age:** 3.90 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Sep-2019	14-Nov-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Silvio Santos, a male Pomeranian of 3.9 years old and 3 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 16 Sep 2019 for flea control. Lack of efficacy is suspected because the pet got fleas approximately 2 months after treatment. Another administration of FL was made on 16 Nov 2019 and the dog remains with fleas. FL has been administered every 2 months with no issue (1st adm date not provided). Environment not treated. No further information is available.
22-Nov-2019	UAE; 19BR005533; -; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 7.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	05-Nov-2019	05-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Ted, a male Shih Tzu of 8 years old and 7.5 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 5 Nov 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. According to the reporter, around 50 fleas were found on Ted on 21 Nov 2019. FL has been administered only once in the past, when Ted was a puppy (2011*), with no issue. He is usually bathed once a week.

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ED_005739D_00014391-00083

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** Yes					Environment treated with an unknown product. No further information is available. UPDATE 26 NOV 2019 - Another product against fleas was administered to Ted and he is currently free of ectoparasites. No further information is known.
22-Nov-2019	UAE; 19BR005534; RS; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Nov-2019	19-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Henrique, a male crossbred cat of 7 years old and 4 kg, received one pipette of FRONTLINE SPOT-ON CATS (FL) (lot and exp. date unknown; topical, btw the shoulder blades), administered by the reporter on 19 Nov 2019 for flea treatment. Lack of efficacy is suspected because Henrique remains with fleas and is scratching himself due to the infestation. FL was administered on the past (dose frequency and first administration date not provided) with no issue. Environment treated with Butox®. No further information is available.
21-Nov-2019	UAE; 19BR005539; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner via social media, a cat of 2 months old and unknown signalment received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp date, route and location are unknown) administered by the reporter on Nov 2019* for unknown reason. The cat licked the product and an unknown time post FL administration it experienced hypersalivation . Its current health status is not known. This is the extent of the information available for now.
22-Nov-2019	UAE; 19BR005546; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Nov-2019	09-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Frajola, a male crossbred cat of 1 year old and unknown weight, received one pipette of FRONTLINE PLUS CATS (FL) (007/18A, exp date is unknown, topical, btw the shoulder blades) administered by an unknown person on 9 Nov 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. FL has been administered only once in the past (Mar 2019*) with no issue. Environment not treated. No further information is available.
22-Nov-2019	UAE; 19BR005548; BA; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 12 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not	07-Oct-2019	07-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Juju, a female crossbred dog of 5 years old and 12 kg, received FRONTLINE SPRAY (FL) (001/19A, exp. date unknown; topical, off-label use – whole body except for the head), administered by the reporter on 7 Oct 2019 for flea treatment. Lack of efficacy is suspected because Juju remains with fleas. FL was administered for the first time on 2015 (dose frequency not provided) with no issue. FRONTLINE (pipette presentation – unsubstantiated) was administered in the past with no issue. According to the reporter, Juju was infested for 3 months prior FL administration. Environment not treated. There are other dog and other 7 cats of the same household treated with FL facing the same issue (SLOE cases reported on 19BR005549, 19BR005550 and 19BR005551). No further information is available.

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* indicates Approximate date or weight.

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ED_005739D_00014391-00084

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						respected)					
22-Nov-2019	UAE; 19BR005549; BA; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 7 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	07-Oct-2019	07-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Diana, a female crossbred dog of 2 years old and 7 kg, received FRONTLINE SPRAY (FL) (001/19A, exp. date unknown; topical, off-label use – whole body except for the head) for the first time, administered by the reporter on 7 Oct 2019 for flea treatment. Lack of efficacy is suspected because Diana remains with fleas. FRONTLINE (pipette presentation – unsubstantiated) was administered in the past with no issue. According to the reporter, Diana was infested for 3 months prior FL administration. Environment not treated. There are other dog and other 7 cats of the same household treated with FL facing the same issue (SLOE cases reported on 19BR005548, 19BR005550 and 19BR005551). No further information is available.
22-Nov-2019	UAE; 19BR005550; BA; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 6 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	07-Oct-2019	07-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 male crossbred cats of 2 years old and 6 kg, received FRONTLINE SPRAY (FL) (001/19A, exp. date unknown; topical, off-label use – whole body except for the head) for the first time, administered by the reporter on 7 Oct 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. FRONTLINE (pipette presentation – unsubstantiated) was administered in the past with no issue. According to the reporter, the cats were infested for 3 months prior FL administration. Environment not treated. There are other 2 dogs and other 5 cats of the same household treated with FL facing the same issue (SLOE cases reported on 19BR005548, 19BR005549 and 19BR005551). No further information is available.
22-Nov-2019	UAE; 19BR005551; BA; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 6 kg	5	5	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	07-Oct-2019	07-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 5 mixed crossbred cats from 4 to 5 years old and 6 kg, received FRONTLINE SPRAY (FL) (001/19A, exp. date unknown; topical, off-label use – whole body except for the head), administered by the reporter on 7 Oct 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. FL was administered for the first time on 2015 (dose frequency not provided) with no issue. FRONTLINE (pipette presentation – unsubstantiated) was administered in the past with no issue. According to the reporter, the cats were infested for 3 months prior FL administration. Environment not treated. There are other 2 dogs and other 5 cats of the same household treated with FL facing the same issue (SLOE cases reported on 19BR005548, 19BR005549 and 19BR005550). No further information is available.
25-Nov-2019	UAE; 19BR005554; PR; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Month(s)	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	17-Nov-2019	17-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Milu, a female small crossbred dog of 2 months old and 2.3 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, btw the shoulder blades - incorrect application), applied by the reporter on 17 Nov 2019, for flea treatment. However, the pet remains with fleas. Environtment treated with Butox®. There is one more dog and two cats in this household and they have no issue. No further information is expected.

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ED_005739D_00014391-00085

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 2.3 kg				**product used ok?:** No (Treatment / vaccination program not respected)					
23-Nov-2019	UAE; 19BR005556; SP; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Nov-2019*	10-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, one cat of unknown signalment was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 10 Nov 2019*, for flea treatment. However, the pet remains with fleas. This is the extent of the information available.
21-Nov-2019	UAE; 19BR005558; SP; Brazil	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 2.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	08-Nov-2019	08-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Priscila, a female Poodle of 13 years old and 2.5 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, base of skull to btw the shoulder blades) applied by the reporter on 8 Nov 2019 for flea treament. Lack of efficacy is suspected because the dog remains with fleas. FL has been administered in the past (last adm date on 2014; dose frequency and 1st adm date not provided) with no issue. Priscila is usually bathed once a week. Environment not treated. Two cats of same household also received FRONTLINE and LOE is suspected (BRA-BIAHPV1P-19BR005559). No further information is available.
21-Nov-2019	UAE; 19BR005559; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 2 - 4 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	08-Nov-2019	08-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female crossbred cats (Julie, 9 months old, approx. 2 kg; Lili, 8 months old, 4 kg) received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, base of skull to btw the shoulder blades) each, for the first time, applied by the retail shop staff member on 8 Nov 2019 for flea treament. Lack of efficacy is suspected because the cats remain with fleas . Environment not treated. One dog of same household also received FRONTLINE and LOE is suspected (BRA-BIAHPV1P-19BR005558). No further information is available.
22-Nov-2019	UAE; 19BR005566; SP; Brazil	**Species:** Canine **Breed:** Dachshund **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 4.5 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	17-Nov-2019*	17-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a dog of unknown signalment received FRONTLINE SPRAY (FL) (006/19A, Apr 2021; route and location are not known) administered by the reporter on 8 Nov 2019*. Lack of efficacy is suspected because 1 week after product application (15 Nov 2019*) multiple fleas were found on the animal. The product was administered again also on 15 Nov 2019* and it was not effective either. FL has been administered in the past (dose frequency and 1st adm date not provided) with no issue. This is the extent of the information available for now. UPDATE 3 Dec 2019 –

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ED_005739D_00014391-00086

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: No (Treatment / vaccination program not respected)					The pet owner was contacted and reported that Fred, a male Dachshund of approx. 3 years old and 4.5 kg, received FRONTLINE SPRAY 100 ML (FL) (topical, whole body) for the first time on 17 Nov 2019* for flea treatment. Lack of efficacy is suspected because fleas continued to be found on the dog. Another application was performed on 23 Nov 2019 and, although there was a decrease on the flea infestation and a partial improvement of the itching (caused by flea allergy), Fred remains with live fleas. Fred was bathed one day before and one day after FL application. Environment treated with Arraze®. There are an unknown number of dogs living in the same household but it is unknown if they were simultaneously treated. No further information is available.
24-Nov-2019	UAE; 19BR005570; MG; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	19-Nov-2019	19-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one cat of unknown signalment received, for the first time, FRONTLINE SPOT-ON (unsubstantiated) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 19 Nov 2019, for flea treatment. However, the pet remains with fleas. This is the extent of the information available.
22-Nov-2019	UAE; 19BR005573; SP; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2016*	2016*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown number of dogs of unknown signalment received FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (2016*). However, the product was not effective (details were not provided). In addition, the owner also complained that FRONTLINE PLUS DOG M had no effect (SLOE case reported on BRA-BIAHPV1P-19BR005497). No further information is expected.
23-Nov-2019	UAE; 19BR005574; BA; Brazil	**Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 6.2 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	17-Nov-2019*	17-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a dog of unknown signalment, received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp. date unknown, route and administration site are unknown), administered by the reporter on date not provided (1 Nov 2019 – chosen at random) for unknown reason. According to the reporter, the product was not effective and the issue was not solved. The current status of the animal is unknown. Environmental factors are not known. This is the extent of the information available for now. UPDATE 29 NOV 2019 - The owner was contacted and reported that Apolo, a male Labrador of 2 months old and 6.2 kg, received, for the first time, one vial of FL, applied by the reporter on 17 Nov 2019*, for tick treatment. However, the pet still has ticks. Environment treated with cypermethrin twice a week. No further information is expected.
23-Nov-2019	UAE; 19BR005575; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	Sep-2019*	Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a dog of unknown signalment, received FRONTLINE (pipette presentation – unsubstantiated) (FL) (lot, exp. date unknown, route and administration site are unknown), administered by the reporter on date not provided Nov 2019* for

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ED_005739D_00014391-00087

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					unknown reason. According to the reporter, the product was not effective. Two other administrations were performed on Sep 2019* and Oct 2019* and both were also not effective. An unknown product was purchased as treatment; however, it is unknown if the issue was solved. FL was administered on the past (dose frequency and first administration date not provided) with no issue. There is a cat of the same household treated with FRONTLINE SPRAY facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005576). This is the extent of the information available for now.
23-Nov-2019	UAE; 19BR005576; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Sep-2019*	Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a cat of unknown signalment, received FRONTLINE SPRAY (FL) (lot, exp. date unknown, route and administration site are unknown), administered by the reporter on Nov 2019* for unknown reason. According to the reporter, the product was not effective. Two other administrations were performed on Sep 2019* and Oct 2019* and both were also not effective. An unknown product was purchased as treatment; however, it is unknown if the issue was solved. FL was administered on the past (dose frequency and first administration date not provided) with no issue. There is a dog of the same household treated with FRONTLINE (pipette presentation – unsubstantiated) facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005575). This is the extent of the information available for now.
23-Nov-2019	UAE; 19BR005583; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of cats of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown are unknown), applied by the reporter on date not specified (Oct 2019*), for unknown reason. However, the product was not effective. The current status of the animals is unknown. FL has been applied for the past 2 years with no issue. This is the extent of the information available.
25-Nov-2019	UAE; 19BR005584; SP; Brazil	**Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** Unknown **Age:** 75.00 Day(s) **Weight:** 4.8 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Nov-2019	11-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Polar, a male Labrador of 75 days old and 4.8 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on 11 Nov 2019, for flea treatment. However, the pet remains with fleas. Fleas have also been found on the owner's bed and in the environment, which has been treated with an insecticide product. There are 3 more dogs in this household that were treated with another product against fleas and they have no issue. No further information is expected.
25-Nov-2019	UAE; 19BR005586; SP; Brazil	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** F **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products	01-Oct-2019	01-Oct-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Greta, a female Jack Russell of 6 months old and 5 kg, received FRONTLINE SPRAY 250 ML (FL) (006/18, exp date is unknown, topical, whole body) for the first time, applied by the reporter on 1 Oct 2019 and 22 Nov 2019 for flea treament. Lack of efficacy is suspected because the pet remains with fleas. Greta is usually

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ED_005739D_00014391-00088

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 6.00 Month(s) **Weight:** 5 kg				**Route:** Topical / Cutaneous **Was the product used ok?:** Yes					bathed once a week. Environment treated with unknown product. No further information is available.
25-Nov-2019	UAE; 19BR005587; -; Brazil	**Species:** Canine **Breed:** Dachshund **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a female Dachshund of other signalment unknown, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date unknown, route and administration site are unknown), administered by the reporter on date not provided (1 Nov 2019 – chosen at random) for unknown reason. According to the reporter, the product was not effective, so Bravecto® was administered and the issue was solved. Environmental factors are not known. This is the extent of the information available for now.
25-Nov-2019	UAE; 19BR005596; -; Brazil	**Species:** Canine **Breed:** Poodle (Standard) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Nov-2019*	08-Nov-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a Poodle of other signalment unknown, received FRONTLINE DOGS (unsubstantiated) (FL) (lot, exp. date unknown, route and administration site are unknown), administered by the reporter on date not provided (1 Nov 2019*) for flea treatment. Lack of efficacy is suspected because , one week after product administration, fleas returned to be seen. The current status of the animal is unkown. The same issue occurred after the previous administration made earlier this year. FL was administered on the past (dose frequency and first administration date not provided) with no issue. Environmental factors are not known. This is the extent of the information available for now.
25-Nov-2019	UAE; 19BR005597; RJ; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 5.5 kg	8	8	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Nov-2019	23-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 8 cats of 3 years old*, 5.5 kg* and mixed sex, received FRONTLINE SPRAY (lot and exp date are unknown, topical, whole body), applied by the reporter on 23 Nov 2019, for flea treatment. However, the animals remain with fleas. Environment treated with an insecticide. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). In addition, the animals also presented a reaction after product application (SAE case reported on BRA-BIAHPV1P-19BR005598). There are 3 dogs in this household that were treated with Bravecto® and they have no issue. No further information is expected.
25-Nov-2019	UAE; 19BR005598; RJ; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 5.5 kg	8	8	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Nov-2019	23-Nov-2019	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, 8 cats of 3 years old*, 5.5 kg* and mixed sex, received FRONTLINE SPRAY (lot and exp date are unknown, topical, whole body), applied by the reporter on 23 Nov 2019, for flea treatment. Soon after product application, the animals presented with drooling and recovered by their own. The owner also complained that her animals remain with fleas (SLOE case reported on BRA-BIAHPV1P-19BR005597). There are 3 dogs in this household that were treated with Bravecto® and they have no issue. No further information is expected.

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ED_005739D_00014391-00089

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
25-Nov-2019	UAE; 19BR005611; RS; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 7.5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Nov-2011*	24-Nov-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female dogs of approx. 7.5 kg (Mini, Lhasa Apso, 9 years old; Pepa, crossbred, 8 years old) received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, administered by the reporter on 18 Nov 2019 for flea/tick control. Lack of efficacy is suspected because fleas are being found on the animals. FL has been administered approx. every 30 days since 2011* with no issue. According to the reporter, Mini is usually bathed once a week and she has flea allergy dermatitis. Pepa is usually bathed once a month. Both are eventually taken for walking outdoors and twice a week they stay in a dog daycare with other dogs. Environment not treated. No further information is available.
23-Nov-2019	UAE; 19BR005612; SC; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 11 - 18 kg	3	3	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Nov-2019	01-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 female crossbred dogs (Pipoca, 4 years old, 11 kg; Luna, 2 years old, 15 kg; Mel, 8 years old, 18 kg), received one pipette of FRONTLINE SPOT-ON DOGS M (FL) (lot, exp. date unknown; topical, btw the shoulder blades) each, administered by the reporter on 1 Nov 2019 for flea and tick treatment. Lack of efficacy is suspected because the dogs remain with fleas, in addition, ticks returned to be seen a few days after administration. FL has been administered every 3-4 months with no issue. Environmental factors are not known. No further information is available.
26-Nov-2019	UAE; 19BR005613; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	30-Sep-2019	30-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Fred, a male crossbred cat of 5 years old and 5 kg, received FRONTLINE SPRAY 100 ML (FL) (002/19, exp date is unknown, topical, btw the shoulder blades and other locations) for the first time, applied by the reporter on 30 Sep, 7 Oct and 1 Nov 2019 for flea treament. Lack of efficacy is suspected because the pet remains with fleas. Before FL, FRONTLINE (pipette presentation – unsubstantiated) used to be administered every 3 months, since date not informed, with no issue. Environment has been treated once a month with Butox®. No further information is available.
25-Nov-2019	UAE; 19BR005617; MG; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 2 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	Jul-2019	Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of dogs of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown) administered by the reporter on 2019* for unknown reason. According to the reporter, the product was not effective. Same issue occurred other times in the past. There is 1 cat of same household that also received FL and LOE is suspected (see BRA-BIAHPV1P-19BR005618). This is the extent of the information available. UPDATE 3 Dec 2019 – The pet owner was contacted and reported that Nina, a female Yorkshire Terrier of 6 months old and 2 kg, received FRONTLINE SPRAY 250 ML (FL) (topical, whole body) for the first time, from Jul 2019 to 10 Nov 2019* (dose frequency once a week), for tick treatment. Lack of efficacy is suspected because ticks continued to be found on the dog after all FL applications and they were manually removed by the pet owner whenever seen. Bravecto® was

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ED_005739D_00014391-00090

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											administered on 18 Nov 2019 and since date not specified (20 Nov 2019*) ectoparasites were no longer found on Nina. The reporter added that Nina used to be bathed on the next day or 2 days after applying FL. Environment treated with unknown product. Another dog of same household has been treated with Bravecto®. No further information is available.
25-Nov-2019	UAE; 19BR005618; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2019*	2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a cat of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown) administered by the reporter on 2019* for unknown reason. According to the reporter, the product was not effective. Same issue occurred other times in the past. An unknown number of dogs of same household also received FL and LOE is suspected (see BRA-BIAHPV1P-19BR005617). This is the extent of the information available.
25-Nov-2019	UAE; 19BR005628; RJ; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	5	5	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Aug-2019*	Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown number of dogs received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Aug 2019*). However, the product was not effective (details are unknown). In addition, the owner also complained that she gave NEXGARD to her dogs and they remain with fleas (SLOE cases reported on BRA-BIAHPV1P-19BR005626 and BRA-BIAHPV1P-19BR005627). No further information is expected.
26-Nov-2019	UAE; 19BR005631; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a dog of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the reporter on date not provided (1 Nov 2019 – chosen at random) unknown reason. According to the reporter, product effectiveness is lasting less than usual. FL was administered in the past (dose frequency and first administration date not provided) with no issue. Environmental factors are not known. This is the extent of the information available for now.
26-Nov-2019	UAE; 19BR005632; MG; Brazil	**Species:** Feline **Breed:** Feline various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 3.9 - 7.9 kg	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Yes	Jun-2019*	Jun-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 3 cats (2 crossbred and a Persian), received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the reporter on date not provided (1 Nov 2019 – chosen at random) for flea treatment. According to the reporter, the product was not effective for the Persian and, for both crossbred, the effectiveness lasted for 2 weeks and then fleas returned to be seen. FL was administered in the past (dose frequency and first administration date not provided) with no issue. Environmental factors are not known. This is the extent of the information available for now. UPDATE 3 DEC 2019 – The owner was contacted and informed that 3 male cats (Fruta, crossbred, 8 years old, 7.9 kg; Sushi, crossbred, 3 years old, 6.8 kg; Breno Lucas, Persian, 11 years old, 3.9 kg), received

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ED_005739D_00014391-00091

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											one pipette of FRONTILINE PLUS CATS, each. Applied by the reporter on Jun 2019*. Since fleas remained to be seen, the owner applied Advocate® and the issue was solved. FL has been administered every 6 months (first administration date not provided) with no issue. The next door neighbor has a dog that is not treated for fleas. The environment has not been treated. No further information expected.
25-Nov-2019	UAE; 19BR005633; RS; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 2 - 5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Nov-2019	23-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two crossbred cats (Edgar, male, 3 years old and 5 kg; Vicky, female 4 months old* and 2 kg), received, for the first time, one vial of FRONTLINE PLUS CATS (FL) (007/18A, unknown exp date, topical, btw the shoulder blades), applied, to each cat, by the reporter on 23 Nov 2019, for flea treatment. However, the animals remain with fleas. Environment not treated. The owner also complained that one of her cats has licked the product and experienced hypersalivation (SAE case reported on BRA-BIAHPV1P-19BR005634). No further information is expected.
25-Nov-2019	UAE; 19BR005634; RS; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 2.000 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Nov-2019	23-Nov-2019	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Vicky, a female crossbred cat of 4 months old and 2 kg, received, for the first time, one vial of FRONTLINE PLUS CATS (007/18A, unknown exp date, topical, btw the shoulder blades), applied by the pet owner on 23 Nov 2019, for flea treatment. Soon after product application, the pet licked the application site and experienced hypersalivation and recovered by her own. Vicky and other cat that lives in this household remain with fleas (SLOE case reported on BRA-BIAHPV1P-19BR005633). No further information is expected.
27-Nov-2019	UAE; 19BR005635; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a female cat of other signalment unknown, received FRONTLINE (unsubstantiated) (FL) (lot and exp. date unknown; topical, btw the shoulder blades), administered by the reporter on date not provided (1 Nov 2019 – chosen at random) for flea treatment. According to reporter, the product was not effective and lack of efficacy is suspected because the cat remains with fleas. There are other dogs of the same household treated with FRONTLINE with no issue. Environmental factors are not known. This is the extent of the information available for now.
26-Nov-2019	UAE; 19BR005639; MG; Brazil	**Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Month(s)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	26-Oct-2019*	16-Nov-2019*	3 Week(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Miucha, a female Pinscher of 8 months old and unknown weight, received, for the first time, FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, 'neck area'), applied by the reporter on 26 Oct 2019*, for flea treatment. The pet was in good health prior to FL and has no history of adverse reactions. Three weeks post product application, the owner noticed that her dog was presenting alopecia at the application site. In addition, the pet developed

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ED_005739D_00014391-00092

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				**Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					porous skin. No vet care was provided. This is the extent of the information available.
27-Nov-2019	UAE; 19BR005644; RS; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Neutered **Age:** 1.20 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Nov-2019	17-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Estrela, a spayed female crossbred cat of 1.2 years old and 5 kg, received FRONTLINE SPOT-ON CAT (FL) (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, administered by the reporter on 17 Nov 2019 for flea treatment. According to reporter, the product was not effective and lack of efficacy is suspected because the cat remains with fleas . Estrela has outdoor access once a week. There are 2 dogs of the same household treated with NEXGARD with no issue. Environment treated with unknown product. The reporter mentioned another SLOE case involving a cat that received FRONTLINE (see case BRA-BIAHPV1P-19BR005645).
27-Nov-2019	UAE; 19BR005645; RS; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by a pet owner's related person, a cat of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (1 Nov 2019 – chosen at random) for unknown reason. According to the reporter, the product was not effective. The current status of the animal is unknown. FL was administered in the past (dose frequency and first administration date not provided) with no issue. Environmental factors are not known. The reporter has one cat facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005644). This is the extent of the information available for now.
27-Nov-2019	UAE; 19BR005646; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** 4 - 6 kg	9	9	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Nov-2019	27-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 9 adult crossbred cats (4 males, approx. 6 kg; 5 females, approx. 4 kg) received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, for the first time, applied by the reporter on 27 Nov 2019 for flea treament. Although the amount of fleas has decreased post FL administration, lack of efficacy is suspected because the ectoparasites are still being found on the animals. Environment recently treated with Triatox® and an unknown product. A dog of same household received FRONTLINE and LOE is also suspected (BRA-BIAHPV1P-19BR005647). No further information is available.
27-Nov-2019	UAE; 19BR005647; SP; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 27 kg*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	27-Nov-2019	27-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Cookie, a male crossbred dog of 10 years old and 27 kg, received one pipette of FRONTLINE PLUS DOGS L (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, applied by the reporter on 27 Nov 2019 for flea treament. Although the amount of fleas has decreased post FL administration , lack of efficacy is suspected because the ectoparasites are still being found on the animal. Environment recently treated with Triatox® and an unknown product. Nine cats of same household received FRONTLINE and LOE is also suspected (BRA-BIAHPV1P-19BR005646). No further information is available.

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ED_005739D_00014391-00093

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					
27-Nov-2019	UAE; 19BR005648; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a female cat of other signalment unknown, received FRONTLINE PLUS CAT (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (1 Nov 2019 – chosen at random) for flea control. According to the reporter, the product was not effective, so lack of efficacy is suspected because the pet is with fleas and is scratching itself due to the ectoparasite. Environmental factors are not known. This is the extent of the information available for now.
26-Nov-2019	UAE; 19BR005649; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 18 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Aug-2019*	Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Nov 2019*), for flea/tick treatment. According to the owner, the product is effective against fleas, but the product does not work against ticks. The pet remains with attached ticks. The owner usually takes her pet for a walk and she sees ticks climbing on her dog. FL was applied 4 times and the owner believes that it was not effective (dose frequency is unknown and first application was not provided).The owner used to apply FL in the past with no issue. Environmental factors are not known. No further information is known. UPDATE 10 DEC 2019 - The owner was contacted and reported that Bidu, a male medium crossbred dog of 3 years old and 18 kg, was treated with one vial of FRONTLINE PLUS DOG M. However, he remained with ticks. So, she administered NEXGARD (unsubstantiated) and Bidu is currently free of ticks. The owner also commented that she has three other dogs that also received FRONTLINE and they experienced similar issue (SLOE cases reported on BRA-BIAHPV1P-19BR005971, BRA-BIAHPV1P-19BR005972 and BRA-BIAHPV1P-19BR005973). No further information is expected.
28-Nov-2019	UAE; 19BR005650; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 2.5 - 5 kg	3	3	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Nov-2019	14-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 female crossbred cats (Suzi, 2.5 kg, 10 years old; Simone, 5 kg, 1 year old; Estopa, 4 kg, 9 years old) received FRONTLINE SPRAY 100 ML (FL) (006/19A, exp date is unknown, topical, whole body) applied by the reporter on 14 Nov 2019 for flea treament. Lack of efficacy is suspected because the cats remain with fleas. According to the reporter, the animals stopped scratching themselves for 2 days post FL administration. Environment not treated. One dog of same household also received FL and LOE is suspected (BRA-BIAHPV1P-19BR005651). No further information is available.
28-Nov-2019	UAE; 19BR005651; SP; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 20 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous	14-Nov-2019	14-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Betão, a male crossbred dog of 2 years old and approx. 20 kg, received FRONTLINE SPRAY 100 ML (FL) (006/19A, exp date is unknown, topical, whole body) applied by the reporter on 14 Nov 2019 for flea treament. Lack of efficacy is suspected because the dog remains with fleas. According to the reporter, the animal stopped scratching himself for 2 days post FL administration. Environment not treated. Three cats of same household also

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ED_005739D_00014391-00094

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					received FL and LOE is suspected (BRA-BIAHPV1P-19BR005650). No further information is available.
27-Nov-2019	UAE; 19BR005652; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 4 cats of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (1 Nov 2019 – chosen at random) for unknown reason. According to the reporter the product was not effective . It is unknown if the issue was solved. Environmental factors are not known. This is the extent of the information available for now.
27-Nov-2019	UAE; 19BR005653; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Aug-2019*	Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a cat of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (Aug 2019 – chosen at random) for unknown reason. According to the reporter the product was not effective . It is unknown if the issue was solved. Environmental factors are not known. This is the extent of the information available for now.
27-Nov-2019	UAE; 19BR005660; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of dogs of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (Nov 2019 – chosen at random) for unknown reason. According to the reporter the product was not effective. It is unknown if the issue was solved. FL was administered once in the past (date not provided) with no issue. Environmental factors are not known. This is the extent of the information available for now.
27-Nov-2019	UAE; 19BR005661; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of cats of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (1 Nov 2019 – chosen at random) for unknown reason. According to the reporter the product was not effective. It is unknown if the issue was solved. FRONTLINE was administered once in the past (date not provided) with no issue. Environmental factors are not known. This is the extent of the information available for now.

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* indicates Approximate date or weight.

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ED_005739D_00014391-00095

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
27-Nov-2019	UAE; 19BR005666; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 4 cats of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (Nov 2019 – chosen at random) for flea treatment. According to the reporter the product was not effective and lack of efficacy is suspected because the cats remain with fleas. Environment treated with unknown product. This is the extent of the information available for now.
27-Nov-2019	UAE; 19BR005667; RJ; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 10.00 Month(s) **Weight:** 4 - 6 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Sep-2019*	Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of cats received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Nov 2019*). However, the product was not effective. This is the extent of the information available. UPDATE 3 Dec 2019 – The pet owner was contacted and reported that 2 crossbred cats (Spike, male, 10 months old and 4 kg; Espoleta, 3 years old and 6 kg) received one pipette of FRONTLINE PLUS CATS (FL) (topical, btw the shoulder blades) each, for the first time on Sep 2019 for flea treatment. The cats remain with fleas. According to the reporter, they don't have outdoor access. Environment not treated. There an untreated cat living in the same household. No further information is available.
27-Nov-2019	UAE; 19BR005668; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 2 cats of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (Nov 2019 – chosen at random) for unknown reason. According to the reporter the product was not effective . It is unknown if the issue was solved. Environmental factors are not known. This is the extent of the information available for now.
27-Nov-2019	UAE; 19BR005669; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one cat of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Nov 2019*). However, the pet remained with fleas, so the owner applied another product against fleas and no more fleas were reported. This is the extent of the information available.
27-Nov-2019	UAE; 19BR005672; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of dogs of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by

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ED_005739D_00014391-00096

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					the pet owner on date not provided (Nov 2019 – chosen at random) for unknown reason. According to the reporter the product was not effective. It is unknown if the issue was solved. Environmental factors are not known. This is the extent of the information available for now.
27-Nov-2019	UAE; 19BR005673; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of cats of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Nov 2019*). However, the product was not effective. The owner also mentioned that she applied FRONTLINE on her dogs and the product did not work as well (SLOE case reported on BRA-BIAHPV1P-19BR005674). This is the extent of the information available.
27-Nov-2019	UAE; 19BR005674; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of dogs of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Nov 2019*). However, the product was not effective. The owner also mentioned that she applied FRONTLINE on her cats and the product did not work as well (SLOE case reported on BRA-BIAHPV1P-19BR005673). This is the extent of the information available.
27-Nov-2019	UAE; 19BR005675; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of cats of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Nov 2019*). However, the product was not effective. The owner also mentioned that one of ther cats presented a side effect (SAE case reported on BRA-BIAHPV1P-19BR005676). This is the extent of the information available.
27-Nov-2019	UAE; 19BR005676; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner via social media, one cat of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Nov 2019*). After product application (exact time to onset is unknown), the pet presented application site alopecia and application site pain. The current status of the animal is unknown. The owner also mentioned

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ED_005739D_00014391-00097

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products **Route:** unknown **Was the product used ok?:** Unknown to Company					that her cats remain with fleas (SLOE case reported on BRA-BIAHV1P-19BR005675). This is the extent of the information available.
27-Nov-2019	UAE; 19BR005677; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 6 kg	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Aug-2018*	Aug-2018*	N/A	D-D	Suspected Adverse Event: As reported by the pet owner via social media, a cat of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date and location are unknown; topical route) administered by the reporter on Jul 2019* for unknown reason. Alopecia at the application site was experienced an unknown time after FL administration. The patient's current status is unknown. An unknown number of cats of same household also received FL with no issue. This is the extent of the information available for now. UPDATE 2 Dec 2019 – The pet owner was contacted and reported that Godá, a male cat of unknown breed, 6 years old and 6 kg*, received one pipette of FRONTLINE PLUS CATS (FL) (topical, btw the shoulder blades) on Aug 2018*. Godá was taken to the veterinarian and, according to the reporter, the DVM informed that the alopecia at the application site was an 'allergy'. The growth of the hair occurred an unknown time later (Sep 2018*). FL has been administered only once in the past (date not informed) with no issue. Another cat of the same household simultaneously received FL with no issue. No further information is available.
27-Nov-2019	UAE; 19BR005678; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a female dog of other signalment unknown, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (Nov 2019 – chosen at random) for flea and tick control. According to the reporter the product was not effective and lack of efficacy is suspected because fleas and ticks are eventually found on the dog. It is unknown if the issue was solved. Environmental factors are not known. There are other 2 cats of the same household treated with FL the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005679). This is the extent of the information available for now.
27-Nov-2019	UAE; 19BR005679; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 2 cats of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (Nov 2019 – chosen at random) for flea and tick control. According to the reporter the product was not effective and lack of efficacy is suspected because fleas and ticks are eventually found on the cat. It is unknown if the issue was solved. Environmental factors are not known. There is another dog of the same household treated with FL facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005678). This is the extent of the information available for now.
27-Nov-2019	UAE; 19BR005682; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of cats of unknown signalment, received FRONTLINE (pipette presentation - unsubstantiated) (FL) (lot, exp. date, route and administration site

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ED_005739D_00014391-00098

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				12% SPOT ON **Other products used:** FIPRONIL SPRAY; **Route:** unknown **Was the product used ok?:** Unknown to Company					are unknown), administered by the reporter on date not provided (Oct 2019*) for unknown reason. According to the reporter the product was not effective and lack of efficacy was suspected because one day after administration, live fleas were seen on the cats. FRONTLINE SPRAY (lot, exp. date, route and administration site are unknown) was also administered on date not provided (Nov 2019*) and same issue occurred. It is unknown if the issue was solved. Environmental factors are not known. This is the extent of the information available for now.
27-Nov-2019	UAE; 19BR005685; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 6 - 9.5 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Jan-2018*	Jan-2018*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two male dogs (Teco, Poodle, 13 years old and 6 kg; Preto, 6 years old and 9.5 kg) received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied, to each dog, by the reporter on Jan 2018*. However, the product was not effective (details were not provided). The owner also complained that she administered NEXGARD to her dogs and they remained with ticks (SLOE case reported on BRA-BIAHPV1P-19BR005684). No further information is expected.
27-Nov-2019	UAE; 19BR005687; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of cats received FRONTLINE 'pipette' (unsubstantiated) (lot,exp date, route and location are unknown), applied by the reporter on date not specified (Oct 2019*). However, the product is not effective. The owner also mentioned that FRONTLINE does not work on dogs as well (SLOE case reported on BRA-BIAHPV1P-19BR005688). In addition, the owner believes that the pipettes came underfill (TPC reported on PRID 542990). No further information is available.
27-Nov-2019	UAE; 19BR005688; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of dogs received FRONTLINE 'pipette' (unsubstantiated) (lot,exp date, route and location are unknown), applied by the reporter on date not specified (Oct 2019*). However, the product was not effective. The owner also mentioned that FRONTLINE does not work on cats as well (SLOE case reported on BRA-BIAHPV1P-19BR005687). In addition, the owner believes that the product came underfill (TPC reported on PRID 542990). No further information is available.
27-Nov-2019	UAE; 19BR005689; RJ; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** - **Age:** 30.00 Day(s) **Weight:** 300 gms	1	1	1	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous	20-Nov-2019*	20-Nov-2019*	0 Day(s)	D-A	Suspected Adverse Event: As reported by the veterinarian, a rescued male kitten of 30 days old and 300 g, was treated, for the first time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the groomer on date not specified (20 Nov 2019*), for flea treatment. It is unknown if the pet was in good health prior to FL. According to the owner, the pet had been wrapped with wet fur in a blanket for 3 hours because it had been hypothermic after FL application. Prostration and apathy have

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ED_005739D_00014391-00099

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					also occurred 2 hours post product application. The cat was taken to other vet clinic and remained hospitalized in a heated mattress to provide extra warmth for him, but it died on the following day. No necropsy was performed. This is the extent of the information available.
27-Nov-2019	UAE; 19BR005690; RJ; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 450 gms	1	1	1	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	26-Nov-2019	27-Nov-2019	1 Day(s)	D-A	Suspected Adverse Event: As reported by the pet owner, Britney, a female cat of 450 g*, was treated, for the first time, with FRONTLINE SPRAY (lot and exp date are unknown, topical, 1 to 2 spray pumps applied on back, neck and tail), administered by the husband's owner on 26 Nov 2019. One day post product application, Britney presented with diarrhea. She also tried to stand up, but she kept falling over because she was very weak. The cat was taken to the vet and experienced hypothermia and convulsion. The vet suspected that FL could be toxic for her of may be she was presenting 'fleas disease'. However, she died on the same day and no necropsy was performed. According to the owner, Britney had been rescued from the streets on 19 Oct 2019. She had history of respiratory disorder, was treated and was been monitored by a vet. No further information is available.
28-Nov-2019	UAE; 19BR005691; SE; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 2 - 5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Sep-2019*	Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two female adult crossbred cats (Agata, 2 kg; Espaca, 5 kg) received one vial of FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied, to each cat, by the reporter 2 months ago (Sep 2019*), for flea treatment. However, the animals remain with fleas. Environment treated with deltamethrin. FL has been applied every 2 months since date not specified. The animals have no outdoor access. There is one untreated cat in this household and it is unknown if it has fleas. No further information is expected.
28-Nov-2019	UAE; 19BR005693; SC; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 1.5 - 5 kg	3	3	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	01-Nov-2019	01-Nov-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 crossbred cats (Maze, female, 3 years old, 3 kg; Nemes, male, 2 years old, 5 kg; James, 3 months old, 1.5 kg), received FRONTLINE SPRAY 100 ML (FL) (005/18A, exp. date unknown; topical, whole body) for the first time, applied by the reporter on 1 Nov 2019 and on 15 Nov 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. According to the reporter, the cats were infested for 4 months prior FL administration. Environment treated with unknown product. No further information is available.
28-Nov-2019	UAE; 19BR005697; -; Brazil	**Species:** Canine **Breed:** Retriever Labrador **Sex:** U **Sex qualifier:** Unknown **Age:** -	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a Labrador of other signalment unknown, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (Nov 2019 – chosen at random) for unknown reason. According to the reporter the product was not effective. It is unknown if the issue was solved. Environmental

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ED_005739D_00014391-00100

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products **Route:** unknown **Was the product used ok?:** Unknown to Company					factors are not known. This is the extent of the information available for now.
28-Nov-2019	UAE; 19BR005699; RJ; Brazil	**Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Dec-2018*	Dec-2018*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Eliza, a female Poodle Toy of 1 year old and 4 kg*, received, for the first time, one vial of FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on Dec 2018*, for flea treatment. However, the animal remained with fleas. The pet is currently free of fleas because NEXGARD has been administered. Environment not treated. The pet has no outdoor access. No further information is expected.
29-Nov-2019	UAE; 19BR005700; SP; Brazil	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	30-Oct-2019*	14-Nov-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Alvin, a male Maltese of 9 years old and 6 kg, received FRONTLINE SPRAY 100 ML (FL) (002/18A, exp. date unknown; topical, whole body), applied by the reporter on 30 Oct 2019* for flea control. Lack of efficacy is suspected because the pet got fleas approximately 2 weeks after treatment. Another administration was made on 14 Nov 2019 and the dog remains with fleas. FL has been administered every 15 days (first administration date not provided) when the dog comes back from the bath at a retail shop. Environment not treated, however the reporter added that FL was applied on the pet's bed. No further information is available.
29-Nov-2019	UAE; 19BR005702; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a cat of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (Nov 2019 – chosen at random) for flea treatment. Lack of efficacy is suspected because the cat remains with fleas. According to the reporter, the infestation status actually got worse after product administration. Environmental factors are not known. This is the extent of the information available for now.
29-Nov-2019	UAE; 19BR005703; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 4 - 6 kg	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products	01-Nov-2019*	01-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a cat of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on 20 Nov 2019* for flea treatment. Lack of efficacy is suspected because the cat remains with fleas. On Oct 2019* another administration was performed and was also not effective . There are an unknown number of cats of the same household treated

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* indicates Approximate date or weight.

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ED_005739D_00014391-00101

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** Unknown to Company					with FL with no issue. Environmental factors are not known. This is the extent of the information available for now. UPDATE 3 DEC 2019 – The owner was contacted and informed that 3 crossbred cats (Francisco, male, 17 years old, 4 kg; Bento, male, 2 years old, 5 kg; Clotilde, female, 3 years old, 6 kg), received one pipette of FRONTLINE PLUS CATS (topical) each, on 1 Nov 2019*. As the cats remained with fleas, another administration was performed on 12 Nov 2019*. It is unknown if the issue was solved. Environment has not been treated. No further information is available.
28-Nov-2019	UAE; 19BR005704; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 6 - 8 kg*	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Nov-2019	21-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two dogs (Fany, a female Shih Tzu of 8 kg* and unknown age; Brezee, a female dog of 6 kg and unknown age) were treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied, to each dog, by the reporter on 21 Nov 2019, for flea/tick treatment. However, the animals remain with ectoparasites. Environment not treated. FL has been applied every 2 months with no issue since date not specified. No further information is expected.
27-Nov-2019	UAE; 19BR005705; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a cat of other signalment unknown, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (Nov 2019 – chosen at random) for unknown reason. According to the reporter the product was not effective. It is unknown if the issue was solved. Environmental factors are not known. This is the extent of the information available for now.
27-Nov-2019	UAE; 19BR005706; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Jun-2018*	Jun-2018*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of cats of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (Nov 2019 – chosen at random) for unknown reason. According to the reporter the product was not effective. So Bravecto® was administered and the issue was solved. Environmental factors are not known. There are other dogs of the same household treated with FL facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005707). This is the extent of the information available for now. UPDATE 3 DEC 2019 – The owner was contacted and informed that 3 male cats of other signalment unknown, received FRONTLINE PLUS CATS on Jun 2018*. Lack of efficacy is suspected because the cats remained with fleas. It is unknown if the issue was solved. The owner also added that the animals live in a house in the countryside. FRONTLINE used to be administered on the past (dose frequency - 2 months, first administration not provided) with no issue. Environment used to be treated with an unknown product.

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ED_005739D_00014391-00102

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
27-Nov-2019	UAE; 19BR005707; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 15 - 45 kg	6	6	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Jun-2018*	Jun-2018*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of female dogs of other signalment unknown, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (Nov 2019 – chosen at random) for unknown reason. According to the reporter the product was not effective. So Bravecto® was administered and the issue was solved. Environmental factors are not known. There are other cats of the same household treated with FL facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005706). This is the extent of the information available for now. UPDATE 3 DEC 2019 – The owner was contacted and informed that 6 female dogs from 15 kg to 45 kg, received FRONTLINE PLUS DOGS (unsubstantiated) on Jun 2018*. Lack of efficacy is suspected because the dogs remained with fleas and ticks, so Bravecto® was administered and the issue was solved. The owner also added that the animals live in a house in the countryside. FRONTLINE used to be administered on the past (dose frequency and first administration not provided) with no issue. Environment used to be treated with an unknown product.
29-Nov-2019	UAE; 19BR005709; SP; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Oct 2019*), for flea treatment. However, the pet remains with fleas. This is the extent of the information available.
28-Nov-2019	UAE; 19BR005710; -; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 23 - 39 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	13-Sep-2019*	03-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 2 dogs (1 crossbred, 1 female Labrador Retriever) of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are not known) administered by the reporter on Nov 2019* for unknown reason. According to the reporter, the product was not effective. This is the extent of the information available for now. UPDATE 6 Dec 2019 – The pet owner was contacted and reported that Carmella, a female Labrador Retriever of 6 years old and 39 kg and Rex, a male crossbred dog of 6 years old and 23 kg, received one pipette of FRONTLINE PLUS DOGS L (FL) each, on 13 Sep 2019* for flea/tick control. Lack of efficacy is suspected because the dogs got ticks approximately 20 days after treatment. FL was applied again on 13 Oct 2019* and on 13 Nov 2019 and the dogs remained with ticks. The ticks were manually removed everytime they were found. It is unknown if Carmella and Rex currently remain with ectoparasites. FL has been administered monthly since date not informed (1st adm date not provided) with no issue. The dogs have outdoor access. Environment started to be treated 15 days ago with Colosso®. No further information is available.
28-Nov-2019	UAE; 19BR005711; SC; Brazil	**Species:** Canine **Breed:** Pinscher (Miniature)	1	1	0	**Product used:** FIPRONIL SPOT ON DOG	28-Nov-2019	28-Nov-2019	0 Day(s)	D-C	Suspected Adverse Event: As reported by the veterinarian, Aika, a female Pinscher of 1.5 years old and 4.4 kg, received FRONTLINE SPOT-ON DOGS (unsubstantiated) (FL) (lot and exp date are

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ED_005739D_00014391-00103

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F **Sex qualifier:** Unknown **Age:** 1.50 Year(s) **Weight:** 4.4 kg				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					unknown, topical, btw the shoulder blades) administered by the the pet owner on 28 Nov 2019 for unknown reason. The animal was in good health prior to FL use, and according to the vet, she has been scratched by a cat on 24 Nov 2019. One hour post FL administration, Aika experienced generalized oedema, papules, abdominal and facial erythema and temperature of 40ºC. She was taken to the vet hospital and dexamethasone and dypirone were administered for treatment. Aika was also bathed for removal of the product. Her current health status is unknown. According to the reporter, there is no possibility that Aika may have been bitten by an insect. FL has been administered only once in the past, on date not informed, with no issue. No further information is available.
29-Nov-2019	UAE; 19BR005712; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL SPOT ON CAT; **Route:** unknown **Was the product used ok?:** Unknown to Company	Jul-2019*	Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a cat of unknown signalment, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on Nov 2019* for flea treatment. Lack of efficacy is suspected because the cat remains with fleas. On Oct 2019* another administration was performed and was also not effective. Environmental factors are not known. This is the extent of the information available for now. UPDATE 5 DEC 2019 – The owner was contacted and informed that, Sofia, a female crossbred cat of 5 years old and approx. 5 kg, received FRONTLINE PLUS CATS on Jul 2019. As Sofia remained with fleas, on Aug 2019 a FRONTLINE SPOT-ON CATS (lot, exp. date, route and administration site are unknown) administration was performed and was also not effective. It is unknown if the issue was solved. Environment not treated. No further information expected.
29-Nov-2019	UAE; 19BR005715; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of dogs of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Nov 2019*). However, the product was not effective. This is the extent of the information available.
29-Nov-2019	UAE; 19BR005724; SP; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 7 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** AFOXOLANER 28.3 MG CHEWABLE TABLETS; **Route:** Topical / Cutaneous **Was the product used ok?:** No	30-Oct-2019*	30-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via retailer, a dog of unknown signalment received NEXGARD (28.3 MG) (X3) (NG) (lot and exp date are unknown) administered by the reporter on 15 Nov 2019* for unknown reason. According to the reporter, the product was not effective. This is the extent of the information available. UPDATE 6 Dec 2019 – The pet owner was contacted and reported that Mel, a female crossbred dog of 1 year old and 7 kg, received one pipette of FRONTLINE SPOT-ON (FL) (unsubstantiated; lot and exp date are unknown; topical, from btw the shoulder blades to the tail; off-label use – incorrect administration) administered by the reporter on 30 Oct 2019* for tick treatment and it was not effective because ticks continued to be found after product administration. Due to this, NG (AAA1962/18, Oct 2020) was given on 6 Nov 2019*, for the first time, and Mel remains with ticks. Environment has been treated

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ED_005739D_00014391-00104

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						(Treatment / vaccination program not respected)					once a day with Amitraz® and gasoline and fire. No further information is available.
01-Dec-2019	UAE; 19BR005726; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 7 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	16-Nov-2019	30-Nov-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female dogs (Pepita, female, Lhasa Apso, 5 years old, 7 kg; Lolita, female, Shih Tzu, 3 months old, unknown weight), received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on 16 Nov 2019 for flea and tick control. Lack of efficacy is suspected because on 30 Nov 2019 fleas were seen when the dogs came back from the bath at a retail shop. Environment not treated. No further information is available.
29-Nov-2019	UAE; 19BR005729; RS; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Nov-2019	10-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 dogs of 5 kg (Bob, male, Brazilian Terrier, 12 years old; Pink, female, Pinscher, 10 years old) received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, base of skull) each, applied by the reporter's son on 10 Nov 2019 for flea treament. Lack of efficacy is suspected because the dogs remain with fleas. FL has been administered once a year (1st adm date not provided) with no issue. Environment treated with Butox®. No further information is available.
02-Dec-2019	UAE; 19BR005734; MG; Brazil	**Species:** Canine **Breed:** West Highland White **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 15 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	29-Nov-2019	30-Nov-2019	1 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Bradock, a male West White Highland Terrier of 10 years old and 15 kg, received one vial of FRONTLINE PLUS DOG XL (FL) (lot and exp date are unknown, topical, btw the shoulder blades - overdose), applied by the reporter on 29 Nov 2019, for flea/tcik treatment. The pet was in good health prior to FL and has history of dermatopathy. One day following product application, Bradock did not want to drink water, so, activated charcoal was given by the reporter and the pet started drinking water again. He also experienced apathy and anorexia. The symptoms are still ongoing. The owner also mentioned that her pet. No vet care was provided. FL was applied in the past with no issue, but the dose frequency is unknown and first application was not provided. The owner still sees fleas on her pet (SLOE case reported on BRA-BIAHPV1P-19BR005735). No further information is available.
02-Dec-2019	UAE; 19BR005735; MG; Brazil	**Species:** Canine **Breed:** West Highland White **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 15 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	29-Nov-2019	29-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bradock, a male West White Highland Terrier of 10 years old and 15 kg, received one vial of FRONTLINE PLUS DOG XL (FL) (lot and exp date are unknown, topical, btw the shoulder blades - overdose), applied by the reporter on 29 Nov 2019, for flea/tick treatment. However, the pet remains with fleas. FL was applied in the past with no issu, but the dose frequency is unknown and first application was not provided. The pet also presented an adverse

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ED_005739D_00014391-00105

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** No (Overdose)					reaction after FL application (SAE case reported on BRA-BIAHPV1P-19BR005734). No further information is expected.
02-Dec-2019	UAE; 19BR005738; SP; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	20-Nov-2019*	20-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Thor, a male crossbred dog of 1 year old and 4 kg, received one pipette of FRONTLINE SPOT-ON (unsubstantiated) (FL) (lot and exp. date; topical, btw the shoulder blades) for the first time, administered by the pet owner on 20 Nov 2019* for flea treatment. Lack of efficacy is suspected because Thor remains with fleas . Environment not treated. No further information available.
02-Dec-2019	UAE; 19BR005739; RJ; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Nov-2019	27-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a female cat of other signalment unknown, received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on 25 Nov 2019* for flea treatment. According to the reporter, the cat remained scratching itself and on 30 Nov 2019, was observed that it remains with fleas. Environmental factors are not known. This is the extent of the information available for now. UPDATE 5 DEC 2019 – The owner was contacted and informed that Lola, a female crossbred cat of 4 years old and 4 kg, received one pipette of FRONTLINE PLUS CATS (topical, btw the shoulder blades) on 27 Nov 2019. Lola remains with fleas. FRONTLINE has been administered every 2 months (first administration date is unknown) with no issue. Environment not treated. No further information expected.
02-Dec-2019	UAE; 19BR005741; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 1 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	25-Nov-2019	25-Nov-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Billy, a male crossbred cat of 2 months old and 1 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (006/18, unknown exp date, topical, whole body), applied by the reporter on 25 Nov 2019, for flea treatment. Some fleas have died and some fleas have been manually removed, however, the owner still sees fleas on his cat. So, on 1 Dec 2019, she applied FL again, but the pet remains with fleas. Environment treated with Butox®. The owner applied FL using her hands unprotected at this last application of the product (Human exposure reported on BRA-BIAHPV1P-19BR005767). No further information is expected.
01-Dec-2019	UAE; 19BR005747; RS; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	11-Nov-2019	11-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 2 dogs of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are not known) administered by the reporter on 11 Nov 2019 for unknown reason. Lack of efficacy is suspected because multiple fleas are being found on the animals and on the environment. FL has been administered in the past (dose frequency and 1st adm date not

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ED_005739D_00014391-00106

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products **Route:** unknown **Was the product used ok?:** Unknown to Company					provided) with no issue. This is the extent of the information available for now.
02-Dec-2019	UAE; 19BR005749; SP; Brazil	**Species:** Feline **Breed:** Feline (DO NOT USE) **Sex:** X **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 2.1 - 4 kg	4	4	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Nov-2019	21-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 mixed crossbred cats from 4 to 6 years old and from 2.1 kg to 4 kg, received one pipette FRONTLINE SPOT-ON CAT (FL) (lot and exp. date unknown, topical, btw the shoulder blades), each, for the first time, administered by the pet owner on 21 Nov 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. Environment treated with Butox®. No further information is available.
02-Dec-2019	UAE; 19BR005750; RS; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 3.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	Jul-2019*	Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Teodora, a male crossbred cat of 8 months old and 3.5 kg*, received, for the first time, one vial of FRONTLINE PLUS (unsubstantiated) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on Jul 2019, for flea treatment. However, the owner continued to see fleas on her animal. On Oct 2019, another product against fleas was applied and the number of fleas has decreased. Environment treated with Jimo®. The pet has no outdoor access. No further information is expected.
02-Dec-2019	UAE; 19BR005752; RS; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Month(s) **Weight:** 2 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Nov-2019	25-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Aureliano, a male crossbred cat of 5 months old and 2 kg, received FRONTLINE PLUS CATS (FL) (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, administered by the pet owner on 25 Nov 2019 for flea and tick treatment. Lack of efficacy is suspected because the cat remains with fleas. Environment not treated. No further information is available.
03-Dec-2019	UAE; 19BR005757; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Month(s) **Weight:** 1.25 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	21-Nov-2019	21-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Milk, a female neutered crossbred cat of 4 months old and 1.25 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, administered by the pet owner on 21 Nov 2019 for flea treatment. According to the reporter, the product was not effective and lack of efficacy is suspected because the cat remains with fleas. The flea infestation started 3 months ago. Environment treated with Butox®. There are 3 dogs of the same household treated with NEXGARD with no issue. No further information is available.

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* indicates Approximate date or weight.

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Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014391-00107

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					
03-Dec-2019	UAE; 19BR005758; PR; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 5.57 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	24-Nov-2019	24-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Luna Maria, a female Shih Tzu of 4 years old and 5.57 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, administered by the pet owner on 24 Nov 2019 for flea treatment. According to the reporter, the product was not effective and lack of efficacy is suspected because the dog remains with fleas. Environment treated with Butox®. No further information is available.
02-Dec-2019	UAE; 19BR005761; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 1.5 - 2 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	28-Nov-2019	28-Nov-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 male crossbred cats of 3 months old (Colosso, 1.5 kg; Boris, 2 kg) received FRONTLINE SPRAY 100 ML (FL) (006/19, exp date is unknown, topical, whole body) each, for the first time, applied by the reporter on 28 Nov 2019 for flea treament. As the fleas continued to be found on the cats, FL was applied once again on 30 Nov 2019 and it was no effective as well; so, lack of efficacy is suspected. The animals are usually bathed every 2 weeks. Environment not treated. No further information is available.
03-Dec-2019	UAE; 19BR005790; PR; Brazil	**Species:** Canine **Breed:** Rottweiler **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 50 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Nov-2019	22-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Hulk, a male Rottweiler of 2 years old and 50 kg, received one pipette of FRONTLINE PLUS DOG XL (FL) (lot and exp. date unknown; topical, btw the shoulder blades), administered by the pet owner on 22 Nov 2019 for flea treatment. According to the reporter, the product was not effective and lack of efficacy is suspected because the dog remains with fleas. FL was administered in the past (dose frequency and first administration date not provided) with no issue. Environmental factors are not known. No further information is available.
05-Dec-2019	UAE; 19BR005791; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Neutered **Age:** 1.50 Year(s) **Weight:** 3 - 4.5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	Mar-2019*	Mar-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 neutered female crossbred cats (Jacira, 3 years old, 4.5 kg; Neguinha, 1.5 years old, 3 kg), received one pipette of FRONTLINE CATS (unsubstantiated) (FL) (lot and exp. date unknown; topical, btw the shoulder blades) each, for the first time, administered by the pet owner on Mar 2019* for flea treatment. According to the reporter, the product was not effective and lack of efficacy is suspected because the cats remained with fleas. Comfortis® was administered and the issue was solved. The reporter mentioned another 2 SLOE cases, however no valid patient info was provided. Environment not treated. No further information is available.

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ED_005739D_00014391-00108

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					
05-Dec-2019	UAE; 19BR005792; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	01-Nov-2019*	01-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pecia, a female crossbred cat of 2 years old and 4 kg, received FRONTLINE SPRAY 250 ML (FL) (lot and exp. date are unknown) for the first time, administered by the pet owner on 1 Nov 2019*, 8 Nov 2019* and 15 Nov 2019* (topical, whole body) and 22 Nov 2019* (topical, btw the shoulder blades; off-label use – incorrect administration) for flea treatment. Lack of efficacy is suspected because the cat remains with fleas. Environment not treated with specific product, however vacuum cleaner was used. No further information is available.
04-Dec-2019	UAE; 19BR005794; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 3 - 7 kg	6	6	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Nov-2019*	09-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, 6 cats of unknown signalment, received FRONTLINE SPRAY (FL) (006/19, Apr 2021; route and administration site are unknown), administered by the pet owner on date not specified (1 Nov 2019 – chosen at random) for flea treatment. Lack of efficacy is suspected because the cat remains with fleas. According to the reporter, the fleas actually increased in quantity after product administration. FL was administered in the past (dose frequency and first administration date not provided) with no issue. Environmental factors are not known. This is the extent of the information available for now. UPDATE 9 DEC 2019 – The owner was contacted and informed that 6 mixed crossbred cats from 2 years old to 16 years old and from 3 kg to 7 kg, received FRONTLINE SPRAY 100 ML (topical, whole body) on 9 Nov 2019*. The cats remain with fleas. FL has been administered approximately every 4 months and the owner complained that the previous administration performed on Jul 2019* was also not effective (SLOE case reported on BRA-BIAHPV1P-19BR006001). Environment treated with unknown product. No further information is available.
04-Dec-2019	UAE; 19BR005808; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 3.5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	13-Nov-2019	13-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female crossbred cats of 3.5 kg (Greice Kelly, 2 years old; Mary Jane, 6 years old) received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, applied by the reporter on 13 Nov 2019 for flea treament. Lack of efficacy is suspected because fleas continued to be found on the cats. Due to the persistence of flea infestation, on 25 Nov 2019 Comfortis® was administered and since 26 Nov 2019 ectoparasites were no longer found. FL has been administered every 3 months (1st adm date not provided) with no issue. Environment treated with Butox®. No further information is available.
04-Dec-2019	UAE; 19BR005812; SP; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	24-Nov-2019	01-Dec-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a female dog of 4 kg (other signalment is unknown) received FRONTLINE PLUS DOGS S (FL) (lot, exp date, route and location are not known) for the first time, administered by the reporter on 24 Nov 2019 for unknown reason. Lack of efficacy is suspected because 1 live flea was seen on the

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ED_005739D_00014391-00109

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 10.00 Month(s) **Weight:** 3.5 kg				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					dog 1 Dec 2019 and since 4 Dec 2019 multiple fleas are being found on it. This is the extent of the information available for now. UPDATE 9 Dec 2019 – The pet owner was contacted and reported that Amora, a female Yorkshire Terrier of 10 months old and 3.5 kg, received one pipette of FL (topical, btw the shoulder blades) for the first time, for flea treatment. NEXGARD® was administered on 6 Dec 2019* because fleas continued to be found on Amora and the issue was solved. Environment not treated. No further information is available.
05-Dec-2019	UAE; 19BR005813; SP; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** 2 - 5 kg	14	14	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Oct-2019*	05-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 14 mixed adult crossbred cats of 2 kg to 5 kg, received FRONTLINE SPRAY 250 ML (FL) (lot and exp. date unknown; topical, whole body), administered by the pet owner 2 months ago (5 Oct 2019*) for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. FL was administered in the past (dose frequency and first administration date not provided) with no issue. Environment treated weekly with Butox®. This is the extent of the information available for now.
03-Dec-2019	UAE; 19BR005816; RS; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 3.5 - 6.5 kg	3	3	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	30-Oct-2019*	30-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 crossbred cats (Chico, male, 13 years old, 4.2 kg; Ci, female, 13 years old, 3.5 kg; Nil, male, unknown age and 6.5 kg) received one pipette of FRONTLINE SPRAY 250 ML (FL) (004/18A, exp date is unknown, topical, whole body) each, for the first time, applied by the reporter on 30 Oct 2019*, 15 Nov 2019* and 25 Nov 2019* for flea treament. Lack of efficacy is suspected because the cats remain with fleas. Some fleas were manually removed by the reporter. The cats have outdoor access. Environment not treated. No further information is available.
06-Dec-2019	UAE; 19BR005824; RJ; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 1.20 Year(s) **Weight:** 2 - 9 kg*	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Nov-2019*	16-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 2 dogs (Dachshund and Pinscher) weighting less than 10 kg, received one vial of FRONTLINE SPOT-ON DOG S (lot, exp date, route and location are unknown), applied, to each dog, by the reporter on date not specified (Dec 2019*). However, the product was not effective (details are unknown). The current status of the animals is unknown. This is the extent of the information available. UPDATE 16 Dec 2019 – The pet owner was contacted and reported that Tiquinho, a male Pinscher, 12 years old and 2 kg and Mel, a female Dachshund of 1.2 years old and 9 kg, received FL (topical, btw the shoulder blades) for the first time on 16 Nov 2019* for flea/tick treatment. Ticks were no longer found, however, the dogs remain with fleas. Tiquinho has outdoor access. Environment not treated. No further information is available.
05-Dec-2019	UAE; 19BR005838; SP; Brazil	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products	02-Nov-2019	23-Nov-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Benny, a male Poodle of 3 years old and 9.2 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (019/18A, unknown exp date), topical, btw the shoulder blades, applied by the reporter on 2 Nov 2019, for flea/tick control. Lack of efficacy is suspected because the dog got fleas 3 weeks after treatment. Another

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ED_005739D_00014391-00110

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 3.00 Year(s) **Weight:** 9.2 kg				**Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					administration of FL was made on 20 Nov 2019. However, the owner continues to see fleas on her pet. Environment treated with an unknown product. FL has been applied every 28 days since date not specified. No further information is expected.
05-Dec-2019	UAE; 19BR005839; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Dec-2019*	Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one cat of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Dec 2019*). However, the owner still sees fleas on her pet. This is the extent of the information available.
09-Dec-2019	UAE; 19BR005840; -; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 30.00 Month(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Mar-2019*	Mar-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two Billy, a male small crossbred dog of 30 months old and 6 kg*, received one vial of FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on Mar 2019, for flea treatment. However, the owner continued to see fleas on her pet. She administered an oral product and Billy is currently free of fleas. It is unknown if FL was applied in the past. Environment not treated. There is a cat in this household with the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005841). No further information is expected.
09-Dec-2019	UAE; 19BR005841; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 2.5 kg*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Mar-2019*	Mar-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Shayenne, a female crossbred cat of 2 years old and 2.5 kg*, received one vial of FRONTLINE PLUS (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on Mar 2019, for flea treatment. However, the owner continued to see fleas on her pet. She administered an oral product and the cat is currently free of fleas. It is unknown if FL was applied in the past. Environment not treated. There is a dog in this household with the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005840). No further information is expected.
05-Dec-2019	UAE; 19BR005845; PE; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 6.00 Year(s)	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other	04-Dec-2019	04-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 crossbred cats (Chico, male, 6 years old, 6 kg; Nutela, female, 8 years old, 4 kg) received one pipette of FRONTLINE PLUS CATS (FL) (007/18B, exp date is unknown, topical, btw the shoulder blades) each, for the first time, applied by the reporter on 4 Dec 2019 for flea treament. Lack of efficacy is suspected because fleas continued to be found after FL administration. On 8 Dec 2019

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ED_005739D_00014391-00111

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 4 - 6 kg				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					Bravecto® was administered and ectoparasites were no longer found. Environment treated with unknown product and vacuum cleaner. No further information is available.
05-Dec-2019	UAE; 19BR005847; SP; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 16.00 Year(s) **Weight:** 4.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Nov-2019*	29-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Sofia, a female crossbred dog of approx. 16 years old and 4.5 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) applied by the reporter on 29 Nov 2019* for flea treament. Lack of efficacy is suspected because fleas continued to be found after FL administration. On date not specified (2 Dec 2019*) an unknown ectoparasiticide product was administered and fleas were no longer found. FL has been administered in the past (1st adm date and dose frequency not provided) with no issue. Environment treated with Butox®. No further information is available.
05-Dec-2019	UAE; 19BR005849; SP; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 7 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Nov-2019	03-Dec-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Rany, a female Shih Tzu of 8 years old and approx. 7 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknown; topical, btw the shoulder blades), administered by the pet owner on 20 Nov 2019 for flea treatment. Lack of efficacy is suspected because on 3 Dec 2019, fleas returned to be seen. Environment treated with Arraze® on 10 Nov 2019*. Vacuum cleaner is also used in the environment. No further information available for now.
05-Dec-2019	UAE; 19BR005852; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Nov-2019*	10-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female and 2 male cats, received one pipette of FRONTLINE SPOT-ON CAT (lot and exp. date unknown; topical, btw the shoulder blades) each, administered by the pet owner on 10 Nov 2019* for flea treatment. Lack of efficacy is suspected because fleas are still being seen on the cats. Environment not treated. No further information available for now.
06-Dec-2019	UAE; 19BR005855; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 17.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	02-Dec-2019	02-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lyrol, a male crossbred cat of 17 years old and approx. 4 kg, received one pipette of FRONTLINE SPOT-ON CAT (007/18B, exp. date unknown; topical, administration site unknown), administered by the pet owner on 2 Dec 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . FL was administered on the past (dose frequency and first administration date are unknown) with no issue. Environment not treated. No further information available for now.

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ED_005739D_00014391-00112

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
06-Dec-2019	UAE; 19BR005860; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Dec-2019*	Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a female dog of unknown signalment received FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Dec 2019*), for flea/tick treatment. However, the product did not work because her pet remains with ectoparasites. There is also a puppy in this household, but it is unknown if it has been treated with FL. This is the extent of the information available.
06-Dec-2019	UAE; 19BR005862; PR; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 1.50 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Nov-2019	30-Nov-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female crossbred cat of 1.5 years old and approx. 5 kg, received one pipette of FRONTLINE SPOT-ON CATS (lot and exp. date unknown; topical, administration site unknown), administered by the pet owner on 16 Nov 2019 for flea treatment. Lack of efficacy is suspected because on 30 Nov 2019, during a bath, the owner noticed that Mel remains with fleas. FL was administered for the first time on 2018 with no issue. Environment not treated. No further information available for now.
06-Dec-2019	UAE; 19BR005869; MG; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 2 - 4.5 kg	4	4	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Nov-2019	22-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 mixed dogs from 2 to 12 years old and from 2 kg to 4.5 kg, received FRONTLINE SPRAY 250 ML (006/18A, exp. date unknown; topical, whole body), administered by the pet owner on 22 Nov 2019 for flea treatment. Lack of efficacy is suspected because fleas are still being seen on the dogs. FL was administered in the past (dose frequency and first administration date not provided) with no issue. Environment treated with Butox®. No further information available for now.
09-Dec-2019	UAE; 19BR005873; SP; Brazil	**Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	29-Nov-2019	29-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lilica, a female Lhasa Apso of 5 years old and 8 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot, exp date, route and location are unknown), applied by the reporter on 29 Nov 2019, for flea treatment. However, the pet remains with fleas. Environment not treated. FL is only applied when the owner sees fleas (dose frequency is unknown and first application was not provided). There are other dogs in this household with the same issue (SLOE cases reported on BRA-BIAHPV1P-19BR005874 and BRA-BIAHPV1P-19BR005875). No further information is expected.
09-Dec-2019	UAE; 19BR005874; SP; Brazil	**Species:** Canine **Breed:** Border Collie **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 14 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	29-Nov-2019	29-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bolota, a female Border Collie of 8 years old and 14 kg, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot, exp date, route and location are unknown), applied by the reporter on 29 Nov 2019, for flea treatment. However, the pet remains with fleas. Environment not treated. FL is only applied when the owner sees fleas (dose frequency is unknown and first application was not provided). There are other dogs in this household with the

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ED_005739D_00014391-00113

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: unknown **Was the product used ok?:** Unknown to Company					same issue (SLOE cases reported on BRA-BIAHPV1P-19BR005873 and BRA-BIAHPV1P-19BR005875). No further information is expected.
09-Dec-2019	UAE; 19BR005875; SP; Brazil	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 34 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	29-Nov-2019	29-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Tranqueira, a female large crossbred dog of 5 years old and 34 kg, was treated with one vial of FRONTLINE PLUS DOG L (FL) (lot, exp date, route and location are unknown), applied by the reporter on 29 Nov 2019, for flea treatment. However, the pet remains with fleas. Environment not treated. FL is only applied when the owner sees fleas (dose frequency is unknown and first application was not provided). There are other dogs in this household with the same issue (SLOE cases reported on BRA-BIAHPV1P-19BR005873 and BRA-BIAHPV1P-19BR005874). No further information is expected.
07-Dec-2019	UAE; 19BR005876; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	30-Nov-2019*	30-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, 2 dogs of unknown signalment, received FRONTLINE PLUS DOG S (lot, exp. date unknown, route and administration site are unknown), administered by the pet owner on 30 Nov 2019* for flea treatment. According to the reporter, the product was not effective and lack of efficacy is suspected because the dogs remain with fleas. Environmental factors are not known. This is the extent of the information available for now.
06-Dec-2019	UAE; 19BR005884; RS; Brazil	**Species:** Feline **Breed:** Feline various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 4 - 5.4 kg	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	03-Dec-2019	03-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 4 cats of unknown signalment, received FRONTLINE (unsubstantiated) (lot, exp. date unknown, route and administration site are unknown), administered by the pet owner on date not provided (Nov 2019 – chosen at random) for flea treatment. According to the reporter, the product was not effective and lack of efficacy is suspected because the cats remained with live fleas. It is unknown if the issue was solved. Environmental factors are not known. This is the extent of the information available for now. UPDATE 17 DEC 2019 – The owner was contacted and informed that 4 mixed cats (Thor, crossbred, 8 months, 5.4 kg; Romeu, crossbred, 2.5 years old, 4.2 kg; Pandora, Siamese, 1.8 years, 4 kg; Perola, crossbred, 2.5 years old, 4.5 kg), received FRONTLINE SPOT-ON CATS for the first time, on 3 Dec 2019. It was not informed if fleas are still being seen on the cats. Environment treated with K-Othrine® every 15 days. No further information is available.
09-Dec-2019	UAE; 19BR005885; MG; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s)	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical /	25-Nov-2019	02-Dec-2019	1 Week(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Bradok, a male crossbred Yorkshire of 6 years old and 6 kg, received, for the first time, one vial of FRONTLINE SPOT-ON DOG S (FL) (018/18B, unknown exp date, topical, btw the shoulder blades), applied by the reporter on 25 Nov 2019, for flea treatment. The pet was in good health prior to FL and has no history of adverse reactions. One week post FL application, the pet experienced

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ED_005739D_00014391-00114

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 6 kg				Cutaneous **Was the product used ok?:** Yes					application site pruritus and desquamation. No vet care was provided. No further information is available.
08-Dec-2019	UAE; 19BR005890; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, an unknown number of dogs of unknown signalment, received FRONTLINE SPRAY (lot, exp. date, route and administration site are unknown), administered by the pet owner on date not provided (Nov 2019 – chosen at random) for tick treatment. According to the reporter, the product was not effective and lack of efficacy is suspected because the dogs are getting ticks. Environmental factors are not known. This is the extent of the information available for now.
11-Dec-2019	UAE; 19BR005897; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a cat of unknown signalment, received 2 pipettes of FRONTLINE PLUS CATS (lot, exp. date, route and administration site are unknown), administered by the pet owner on dates not provided (Oct-Nov 2019*) for flea treatment. Lack of efficacy is suspected because the cat remains with fleas. Environmental factors are not known. This is the extent of the information available for now.
09-Dec-2019	UAE; 19BR005899; SP; Brazil	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 30 kg	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Nov-2019	14-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lili, a female German Shepherd of 5 years old and 30 kg, received one pipette of FRONTLINE PLUS DOGS L (lot and exp. date unknown, topical, btw the shoulder blades), administered by the pet owner on 14 Nov 2019 for flea treatment. Lack of efficacy is suspected because the dog remains with fleas. There are other 2 dogs of the same household treated with FRONTLINE with no issue. Environment treated with Butox®. There are 2 cats and 1 dog of the same household treated with FRONTLINE facing the same issue (SLOE cases reported on BRA-BIAHPV1P-19BR005900; BRA-BIAHPV1P-19BR005901 and BRA-BIAHPV1P-19BR006074). No further information is available.
09-Dec-2019	UAE; 19BR005900; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 1.50 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Nov-2019	14-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mion, a male crossbred cat of approx. 1.5 years old and 4 kg, received one pipette of FRONTLINE PLUS CATS (lot and exp. date unknown, topical, btw the shoulder blades), administered by the pet owner on 14 Nov 2019 for flea treatment. Lack of efficacy is suspected because the cat remains with fleas. FRONTLINE was administered in the past (dose frequency and first administration date are unknown) with no issue. Environment treated with Butox®. There are 2 dogs and 1 cat of the same household tretated with FRONTLINE facing the same issue (SLOE cases reported on BRA-BIAHPV1P-19BR005899; BRA-BIAHPV1P-19BR005901 and BRA-BIAHPV1P-19BR006074). No further information is available.

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ED_005739D_00014391-00115

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
09-Dec-2019	UAE; 19BR005901; SP; Brazil	**Species:** Feline **Breed:** Siamese **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Nov-2019	14-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Luna, a female Siamese of 3 months old and 3 kg, received one pipette of FRONTLINE PLUS CATS (lot and exp. date unknown, topical, btw the shoulder blades) for the first time, administered by the pet owner on 14 Nov 2019 for flea treatment. Lack of efficacy is suspected because the cat remains with fleas. Environment treated with Butox®. There are 2 dogs and 1 cat of the same household treated with FRONTLINE facing the same issue (SLOE cases reported on BRA-BIAHPV1P-19BR005899; BRA-BIAHPV1P-19BR005900 and BRA-BIAHPV1P-19BR006074). No further information is available.
09-Dec-2019	UAE; 19BR005906; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 1.5 kg	2	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Nov-2019	03-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Simba, a male crossbred cat of 2 months old and 1.5 kg, received one pipette of FRONTLINE SPOT-ON CATS (FL) (017/18A, exp date is unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 3 Nov 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . There is a cat of same household that has been simultaneously treated with FL with no issue. Environment treated with Butox®. No further information is available.
09-Dec-2019	UAE; 19BR005913; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 2.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	05-Dec-2019*	05-Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a female dog of 2.5 kg (other signalment is unknown) received FRONTLINE PLUS DOGS S (FL) (lot, exp date, route and location are not known) administered by the reporter on 5 Dec 2019*. Lack of efficacy is suspected because fleas are being found on the dog. This is the extent of the information is available for now.
10-Dec-2019	UAE; 19BR005923; SC; Brazil	**Species:** Canine **Breed:** Chowchow **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 20 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Dec-2019	05-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Tommy, a male Chowchow of 5 years old and 20 kg, received one pipette of FRONTLINE PLUS DOGS M (FL) (013/18A, exp date is unknown, topical, btw the shoulder blades) applied by the reporter on 5 Dec 2019 for flea treament. Lack of efficacy is suspected because the pet remains with fleas. FL has been administered since 2014, once a year, with no issue. Environment not treated. No further information is available.
10-Dec-2019	UAE; 19BR005928; SC; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** M	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	20-Nov-2019	27-Nov-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nike, a male crossbred dog of 7 years old and 16 kg, received one pipette of FRONTLINE PLUS DOGS M (FL) (lot and exp date are unknown, topical, btw the shoulder blades) applied by the reporter on 20 Nov 2019 for flea treatment. Lack of efficacy is suspected

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ED_005739D_00014391-00116

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** 7.00 Year(s) **Weight:** 16 kg				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					because on 27 Nov 2019 fleas returned to be found on the dog. FL has been administered once a year, usually on summer season, with no issue. The first administration date was not provided. A dog from same household simultaneously received FRONTLINE and LOE is also suspected (see BRA-BIAHPV1P-19BR005929). Environment treated with unknown product. No further information is available.
10-Dec-2019	UAE; 19BR005929; SC; Brazil	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 1.50 Year(s) **Weight:** 7 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Nov-2019	27-Nov-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Poodle of 1.5 year old and 7 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) applied by the reporter on 20 Nov 2019 for flea treatment. Lack of efficacy is suspected because on 27 Nov 2019 fleas returned to be found on the dog. FL has been administered once a year, usually on summer season, with no issue. The first administration date was not provided. A dog from same household simultaneously received FRONTLINE and LOE is also suspected (see BRA-BIAHPV1P-19BR005928). Environment treated with unknown product. No further information is available.
10-Dec-2019	UAE; 19BR005930; MG; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 75.00 Day(s) **Weight:** 2 kg*	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	08-Dec-2019	08-Dec-2019	0 Day(s)	D-C	Suspected Lack of Efficacy Claim: As reported by the pet owner, Loki, a male crossbred cat of 75 days old and 2 kg, received, for the first time, FRONTLINE SPRAY (008/19A, unknown exp date, topical, parts of the body), applied by the reporter on 8 Dec 2019, for flea treatment. At 9 pm, the owner noted that Loki was 'quiet'. Two hours later, he experienced 2 episodes of vomiting. In addition, the pet presented appetite loss. On 9 Dec 2019, he experienced diarrhea. Her cat started having a strange purring sound and his breathing is also different. No vet care was provided. No further information is available.
11-Dec-2019	UAE; 19BR005943; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Dec-2019*	Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a dog of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Dec 2019*). However, the pet remains scratching itself. This is the extent of the information available.
11-Dec-2019	UAE; 19BR005949; SP; Brazil	**Species:** Feline **Breed:** - **Sex:** F **Sex qualifier:** Unknown **Age:** 52.00 Day(s) **Weight:** 840 gms	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous	09-Dec-2019	09-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Tiana a female crossbred cat of 52 days old and 840 g, received FRONTLINE SPRAY (lot and exp. date unknown; topical, various spots, 4 pumps - low dose) for the first time, administered by the pet owner on 9 Dec 2019 for flea treatment. Lack of efficacy is suspected because the cat remains with fleas. Environment not treated. No further information is available.

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ED_005739D_00014391-00117

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: No (Treatment / vaccination program not respected)					
11-Dec-2019	UAE; 19BR005952; SP; Brazil	**Species:** Canine **Breed:** Poodle (Standard) **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 10 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Dec-2019	07-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner vis social media, a Poodle of approx. 10 kg, received FRONTLINE PLUS DOG S (lot, exp. date, route and administration site unknown), administered by the pet owner on 7 Dec 2019 for flea treatment. Lack of efficacy is suspected because the dog remains with fleas and is scratching itself due to the infestation. Environmental factors are not known. No further information is available. UPDATE 17 DEC 2019 – The owner was contacted and informed that Conhaque, a male Poodle of 3 years old and 10 kg, received one pipette of FL (029/18A, exp. date unknown; topical, btw the shoulder blades) for the first time. The dog remained with fleas and scratching himself due to the infestation, so on 15 Dec 2019, NEXGARD (28.3 mg) was administered as treatment and the issue was solved. Environment not treated. No further information is available.
11-Dec-2019	UAE; 19BR005954; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	11-Nov-2019*	11-Dec-2019*	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a cat of unknown signalment, received FRONTLINE PLUS (unsubstantiated) (lot, exp. date, route and administration site unknown), administered by the pet owner on Nov 2019* for flea control. Lack of efficacy is suspected because, one month post administration, fleas are being seen on the cat. Environmental factors are not known. No further information is available.
11-Dec-2019	UAE; 19BR005955; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	05-Dec-2019	05-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a cat of unknown signalment, received FRONTLINE CATS (unsubstantiated) (lot, exp. date, route and administration site unknown), administered by the pet owner on 5 Dec 2019 for flea treatment. Lack of efficacy is suspected because the cat remains with fleas. According to the reporter, fleas actually increased in quantity. Environmental factors are not known. This is the extent of the information available for now.
11-Dec-2019	UAE; 19BR005956; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown	27-Nov-2019	27-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a dog of unknown signalment, received FRONTLINE SPOT-ON DOGS S (lot, exp. date, route and administration site unknown), administered by the pet owner on 27 Nov 2019 for flea treatment. Lack of efficacy is suspected because the dog remains with fleas. According to the reporter, fleas actually increased in quantity. The owner asserts that the product was administered

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ED_005739D_00014391-00118

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				**Was the product used ok?:** Unknown to Company					according to the animal's weight. Environmental factors are not known. There is another dog of the same household treated with FRONTLINE facing the same issue (SLOE case reported o BRA-BIAHPV1P-19BR005957). This is the extent of the information available for now.
11-Dec-2019	UAE; 19BR005957; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	27-Nov-2019	27-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a dog of unknown signalment, received FRONTLINE SPOT-ON DOG M (lot, exp. date, route and administration site unknown), administered by the pet owner on 27 Nov 2019 for flea treatment. Lack of efficacy is suspected because the dog remains with fleas. According to the reporter, fleas actually increased in quantity. The owner asserts that the product was administered according to the animal's weight. Environmental factors are not known. There is another dog of the same household treated with FRONTLINE facing the same issue (SLOE case reported o BRA-BIAHPV1P-19BR005956). This is the extent of the information available for now.
11-Dec-2019	UAE; 19BR005962; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	10	10	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Dec-2019*	Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 10 cats of unknown signalment, received FRONTLINE (unsubstantiated) (lot, exp. date, route and administration site unknown), administered by the pet owner on date not provided (Dec 2019 – chosen at random) for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. Environmental factors are not known. There are 4 dogs of the same household treated with FRONTLINE facing the same issue (SLOE case reported o BRA-BIAHPV1P-19BR005963). This is the extent of the information available for now.
11-Dec-2019	UAE; 19BR005963; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Dec-2019*	Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 4 dogs of unknown signalment, received FRONTLINE (unsubstantiated) (lot, exp. date, route and administration site unknown), administered by the pet owner on date not provided (Dec 2019 – chosen at random) for flea treatment. Lack of efficacy is suspected because the dogs remain with fleas. Environmental factors are not known. There are 10 cats of the same household treated with FRONTLINE facing the same issue (SLOE case reported o BRA-BIAHPV1P-19BR005962). This is the extent of the information available for now.
10-Dec-2019	UAE; 19BR005969; MG; Brazil	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 35 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Dec-2019	01-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female Golden Retriever of 35 kg and unknown age, was treated with FRONTLINE SPRAY (FL) (004/19, unknown exp date, topical, whole body), applied by the reporter on 1 Dec 2019, for tick treatment. However, the pet remains with live ticks. The dog has developed dermatitis due to tick bite. Environment treated with Butox®. There are other dogs in this household that were also treated with FL and they have the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005970). There are two untreated cats in this household with no issue. No further information is expected.

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ED_005739D_00014391-00119

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
10-Dec-2019	UAE; 19BR005970; MG; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	5	5	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Dec-2019	01-Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 5 female dogs (2 Shih Tzus and 3 crossbred dogs - other signalment is unknown) were treated with FRONTLINE SPRAY (FL) (004/19, unknown exp date, topical, whole body), applied by the reporter on 1 Dec 2019, for tick treatment. Howerver, the animals remain with ticks. Environment treated with Butox®. There is one more dog in this household with the same issue (SLOE case reported on BRA-BIAHPV1P-19BR005969). In addition, there are two untreated cats in this household with no issue. No further information is expected.
10-Dec-2019	UAE; 19BR005971; SP; Brazil	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 20 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Negão, a male large crossbred dog of 3 years old and 20 kg, was treated with one vial of FRONTLINE PLUS DOG L (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Nov 2019*), for tick treatment. However, the owner continued to see ticks on his pet. So, she administered NEXGARD (unsubstantiated) and Negão is currently free of ticks. Environmental factors are not known. There are other dogs in this household with similar issue (SLOE cases reported on BRA-BIAHPV1P-19BR005649, BRA-BIAHPV1P-19BR005972 and BRA-BIAHPV1P-19BR005973). No further information is expected.
10-Dec-2019	UAE; 19BR005972; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 16 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Choquito, a male medium crossbred dog of 14 years old and 16 kg, received one vial of FRONTLINE M (unknown if it was Spot-on or Plus) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Nov 2019*), for tick treatment. However, the owner continues to see ticks on his pet. Environmental factors are not known. There are other dogs in this household with similar issue (SLOE cases reported on BRA-BIAHPV1P-19BR005649, BRA-BIAHPV1P-19BR005971 and BRA-BIAHPV1P-19BR005973). No further information is expected.
10-Dec-2019	UAE; 19BR005973; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** 20 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Wisky, a male medium crossbred dog of 9 months old and 20 kg, was treated with one vial of FRONTLINE L (unknown if it was Spot-on or Plus) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Nov 2019*), for tick treatment. However, the owner continues to see ticks on his pet. Environmental factors are not known. There are other dogs in this household with similar issue (SLOE cases reported on BRA-BIAHPV1P-19BR005649, BRA-BIAHPV1P-19BR005971 and BRA-BIAHPV1P-19BR005972). No further information is expected.
10-Dec-2019	UAE; 19BR005975; PE; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F	1	1	0	**Product used:** FIPRONIL SPRAY **Other products**	01-Jul-2018	Jan-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Malu, a female Yorkshire Terrier of 7 years old and approx. 5 kg, received FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, 6-7 pumps 'not on whole body'- off-label use) applied by the reporter on 1 Jan 2019 for ectoparasite control. Lack of efficacy

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ED_005739D_00014391-00120

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** 7.00 Year(s) **Weight:** 5 kg				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					is suspected because on Jan 2019 one tick was found on Malu. NEXGARD was administered and no more ticks were reported. FL has been administered monthly, since 1 Jul 2018, with no issue. Environmental factors are not known. Same patient experienced AE to FL and another BIAH product (see cases BIAHPV1P-19BR005974 and BIAHPV1P-19BR005976 to BIAHPV1P-19BR005979). No further information is available.
10-Dec-2019	UAE; 19BR005979; PE; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** Seresto®; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Aug-2019	01-Aug-2019*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Malu, a female Yorkshire Terrier of 8 years old and 5 kg, received FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body) administered by the reporter on 1 Aug 2019 for ectoparasite control. Seresto® was being concomitantly used by Malu at the occasion. Malu experienced urticarial rash an unknown time after receiving FL. FL use was discontinued and Malu recovered an unknown time later. BIAH contacted the veterinarian and was reported that 'Malu has an intense gastrointestinal sensitivity'. Her level of suspicion of FL is high. FL has been administered in the past from 1 Jul 2018 to 1 Jan 2019 and LOE invoving the same patient was suspected (see BIAHPV1P-19BR005975). Gastrointestinal AEs were also experienced after another BIAH product was administered (see cases BIAHPV1P-19BR005974 and BIAHPV1P-19BR005976 to BIAHPV1P-19BR005978). No further information is available.
11-Dec-2019	UAE; 19BR005988; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 5.5 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Dec-2019	06-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Tom, a male crossbred cat of 2 years old and 5.5 kg, received one pipette of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, applied by the reporter on 6 Dec 2019 for flea treament. Lack of efficacy is suspected because the cat remains with fleas. Environment not treated. No further information is available.
12-Dec-2019	UAE; 19BR005992; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of cats of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Oct 2019*). However, the owner believes that FL is not effective (details are unknown). The current status of the animals was not informed. This is the extent of the information available.
12-Dec-2019	UAE; 19BR005993; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U	8	8	0	**Product used:** FIPRONIL SPOT ON CAT **Other products**	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 8 cats of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not

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ED_005739D_00014391-00121

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				**used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					specified (Nov 2019*). However, the owner believes that FL is not effective (details are unknown). This is the extent of the information available.
13-Dec-2019	UAE; 19BR005995; RJ; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Nov-2019	30-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of cats of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified. According to the owner, the product did not protect the cats nor for one week (details are unknown). This is the extent of the information available. UPDATE 17 DEC 2019 - The owner was contacted and reported that 2 male crossbred cats of unknown signalment received, for the first time, one vial of FRONTLINE SPOT-ON CATS (FRONTLINE) (lot and exp date are unknown, topical, btw the shoulder blades), applied, to each cat, by the reporter on 30 Nov 2019, for flea treatment. Flea infestation 4-5 days prior to FRONTLINE. It is unknown if they remain with fleas. Environmental factors are not known either. The cats have daily outdoor access. There is one more cat in this household that was not treated. No further information is expected.
09-Dec-2019	UAE; 19BR006001; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 3 - 7 kg	6	6	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Jul-2019*	Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 6 mixed crossbred cats from 2 years old to 16 years old and from 3 kg to 7 kg, received FRONTLINE SPRAY (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on Jul 2019* for flea treatment. Lack of efficacy is suspected because the cat remained with fleas. It is unknown if the issue was solved. FL has been administered approximately every 4 months (first administration date not provided) with no issue. FRONTLINE was also administered on 9 Nov 2019* and the same issue occurred (SLOE case reported on BRA-BIAHPV1P-19BR005794). No further information is available.
13-Dec-2019	UAE; 19BR006003; RJ; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Week(s) **Weight:** 200 gms	1	1	1	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Dec-2019	08-Dec-2019	1 Day(s)	D-A	Suspected Adverse Event: As reported by the pet owner, Murio, a male rescued crossbred cat of 2-3 weeks old and 200 g, was treated, for the first time, with FRONTLINE SPRAY (FL) (007/19, unknown exp date, topical, '2 pumps'), applied by the owner' son on 7 Dec 2019, for flea treatment. One day later, the pet started drooling and he straining to defecate. He defecated outside the litter box and became progressively more lethargic. Milk was given to Murio by the owner. He was taken to the vet and a physical examination showed that the kitten's general conditions were not good. Murio was in shock and unresponsive. He also had bradycardia and presented with cachexia. Vomiting and disorientation were also mentioned by the owner. Antitoxic and corticosteroids were administered. The vet tried to warm him up and increase his core body temperature. Some hours later, Murio suffered cardiopulmonary arrest (CPA); CPR was performed and he recovered. However, he experienced another CPA and came to death. No further information is available.
12-Dec-2019	UAE; 19BR006005; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE	13-Nov-2019	13-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female dogs of 'less than 10 kg' (Princesa, crossbred, 6 years; Kiara, Maltese, 4 years old) received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw

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ED_005739D_00014391-00122

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** 4.00 Year(s) **Weight:** 8 kg				9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					the shoulder blades) each, for the first time, applied by the reporter on 13 Nov 2019 for flea treament. Lack of efficacy is suspected because the dogs remain with fleas. Environment not treated. No further information is available.
12-Dec-2019	UAE; 19BR006007; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	02-Dec-2019*	02-Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a dog of unknown signalment received FRONTLINE SPOT-ON DOGS L (FL) (lot, exp date, route and location are unknown) applied by the reporter on 2 Dec 2019* for flea treatment. Lack of efficacy is suspected because fleas are still being found on the animal. FL has been administered in the past (dose frequency and 1st adm date not provided) with no issue. The reporter mentioned that she knows an unknown number of dogs that received FRONTLINE and LOE is also suspected (see BRA-BIAHPV1P-19BR006008). This is the extent of the information available.
12-Dec-2019	UAE; 19BR006008; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by a person related to the pet owner, an unknown number of dogs of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown) applied by an unknown person on 1 Nov 2019* for unknown reason. According to the reporter, the product was not effective. Another dog received FRONTLINE and LOE is also suspected (see BRA-BIAHPV1P-19BR006007). This is the extent of the information available.
12-Dec-2019	UAE; 19BR006009; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 3 cats of unknown signalment received FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown) applied by the reporter on Nov 2019* for unknown reason. According to the reporter, the product was not effective. This is the extent of the information available.
12-Dec-2019	UAE; 19BR006010; -; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** Unknown	5	5	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** FIPRONIL SPRAY; **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 female and 1 male crossbred cats from approx. 1 to 2.4 years old and unknown weight, received one pipette of FRONTLINE SPOT-ON (unsubstantiated) (FL) (lot, exp date, route and location are unknown) each, applied by the reporter on 1 Nov 2019* for flea treatment. Lack of efficacy was suspected because fleas continued to be found on the cats. Due to this, on 28 Nov 2019 FRONTLINE SPRAY (FL SPRAY) (lot and exp date unknown, topical, back) was applied and lack of efficacy is still suspected because same issue occurred. Fleas are currently being found on the animals. Revolution® was purchased but it was not informed if it has been already administered to the cats. Environment treated every 30 days with unknown product. This is the extent of the information

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ED_005739D_00014391-00123

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											available.
13-Dec-2019	UAE; 19BR006014; GO; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 5 - 6 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Nov-2019	29-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 male dogs (Pirulito, Dachshund, approx. 2 years, 6 kg; Floquinho, crossbred, 1 year old, 5 kg), received FRONTLINE SPRAY 250 ML (FL) (001/19A, exp. date unknown; topical, whole body), administered by the pet owner on 29 Nov 2019 for flea treatment. Lack of efficacy is suspected because the dogs remain with fleas . FL was administered on the past (dose frequency and first administration date note provided) with no issue. Environment treated with Barrage®. There is a cat of the same household treated with FRONTLINE facing the same issue (SLOE case reported o BRA-BIAHPV1P-19BR006016). No further information is available.
13-Dec-2019	UAE; 19BR006016; GO; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Nov-2019	29-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a cat of unknown signalment, received FRONTLINE SPRAY 250 ML (FL) (001/19A, exp. date unknown; topical, whole body), administered by the pet owner on 29 Nov 2019 for flea treatment. Lack of efficacy is suspected because the cat remained with fleas . So an unknown product was administered on date not informed (5 Dec 2019*) and the issue was solved. FL was administered on the past (dose frequency and first administration date note provided) with no issue. Environment treated with Barrage®. There are 2 dogs of the same household treated with FRONTLINE facing the same issue (SLOE case reported o BRA-BIAHPV1P-19BR006014). No further information is available.
13-Dec-2019	UAE; 19BR006020; SP; Brazil	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 35 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** Capstar®; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Nov-2019	29-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Dory, a female Golden Retriever of approx. 2 years old and 35 kg, received one pipette of FRONTLINE SPOT-ON DOGS L (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, administered by the pet owner on 29 Nov 2019 for flea treatment. Lack of efficacy is suspected because fleas are still being seen on Dory and she is scratching herself due to the infestation. On 4 Dec 2019, Capstar® as treatment, however it was also not effective and fleas are still being seen . There is another dog of the same household treated with Pulgoff® and the issue was solved. The owner also added that there is a parking lot on the neighborhood with a lot of stray cats. Environment partially treated with Butox®. No further information is available.
13-Dec-2019	UAE; 19BR006021; SP; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 3.8 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	09-Dec-2019*	09-Dec-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Tairone, a male Yorkshire Terrier of 3.8 kg, received FRONTLINE SPRAY 100 ML (002/19A, Dec/2020; topical, whole body), administered by the pet owner on 9 Dec 2019* for flea treatment. Lack of efficacy is suspected because the dog remained with fleas , so another 5 applications were performed on consecutive days (from 10 Dec 2019* to 14 Dec 2019*). The owner added that fleas decreased in quantity; however are still being seen on the dog. FL was administered on the past (dose frequency and first administration date note provided) with no issue. Environment treated with Amitraz every 6 months (last treatment approximately 1 week ago). There are 3 cats of the same household treated with FRONTLINE facing the same issue (SLOE case reported o BRA-BIAHPV1P-19BR006022). No further information is available.
13-Dec-2019	UAE;	**Species:** Feline	3	3	0	**Product used:**	09-Dec-2019*	09-Dec-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3

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ED_005739D_00014391-00124

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19BR006022; SP; Brazil	**Breed:** Feline various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 1.25 - 3.2 kg				FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					female cats (Rubi, Siamese, 3 months old, 1.25 kg; Amora, crossbred, 3 months old, 1.4 kg; unknown name, crossbred, 1.5 years old, 3.2 kg), received FRONTLINE SPRAY 100 ML (002/19A, Dec/2020; topical, whole body), administered by the pet owner on 9 Dec 2019* for flea treatment. Lack of efficacy is suspected because the cats remained with fleas, so another 5 applications were performed on consecutive days (from 10 Dec 2019* to 14 Dec 2019*). The owner added that fleas decreased in quantity; however are still being seen on the cats. FL was administered on the past (dose frequency and first administration date note provided) with no issue. Environment treated with Amitraz every 6 months (last treatment approximately 1 week ago). There is a dog of the same household treated with FRONTLINE facing the same issue (SLOE case reported o BRA-BIAHPV1P-19BR006021). No further information is available.
13-Dec-2019	UAE; 19BR006024; RS; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	23-Nov-2019*	23-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mima, a female crossbred cat of unknown weight and age, received 12 pumps of FRONTLINE SPRAY 100 ML (FL) (002/18, exp date is unknown; topical, unknown location) applied by the reporter on 23 Nov 2019* for flea treament. Lack of efficacy is suspected because the cat remains with fleas. Environment treated with Butox® and Colosso®. There is 1 dog living in the same household and Seresto® is used for flea/tick control. Mima gave birth to 6 kittens that have been also treated with FL and LOE is suspected (see BRA-BIAHPV1P-19BR006025). No further information is available.
13-Dec-2019	UAE; 19BR006025; RS; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** 30.00 Day(s) **Weight:** Unknown	6	6	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	23-Nov-2019*	23-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 6 kittens (4 males, 2 females) of 30 days old (other signalment is unknown) received 1 pump of FRONTLINE SPRAY 100 ML (FL) (002/18, exp date is unknown; topical, unknown location) each, for the first time, applied by the reporter on 23 Nov*, 29 Nov* and 5 Dec 2019* for flea treament. Lack of efficacy is suspected because the cats remain with fleas. Environment treated with Butox® and Colosso®. There is 1 dog living in the same household and Seresto® is used for flea/tick control. The mother of the kittens was also treated with FL and LOE is suspected (see BRA-BIAHPV1P-19BR006024). No further information is available.
13-Dec-2019	UAE; 19BR006026; SP; Brazil	**Species:** Canine **Breed:** Spaniel (Cocker) **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 10 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-May-2019*	30-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Peteleco, a male Cocker Spaniel of 8 years old and approx. 10 kg, received one pipette of FRONTLINE PLUS DOGS M (FL) (lot and exp date are unknown, topical, btw the shoulder blades) applied by the reporter on 22 Nov 2019* for flea control. Lack of efficacy is suspected because the pet got fleas after treatment. FL has been applied every 3 months, since May 2019, with no issue. Environment treated with Butox®. No further information is available.

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ED_005739D_00014391-00125

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
13-Dec-2019	UAE; 19BR006032; PR; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Oct-2019	08-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Militi, a male Shih Tzu of 8 years old and approx. 5 kg, received one pipette FRONTLINE PLUS DOG S (lot and exp. date unknown; topical, btw the shoulder blades), administered by the pet owner on 27 Oct 2019 for flea control. Lack of efficacy is suspected because on 8 Nov 2019* fleas started to be seen on the dog. So on 27 Nov 2019 another administration was performed and on 7 Dec 2019* fleas returned to be seen again on Militi. FL has been administered every 30 days (first administration date not provided) with no issue. Environment not treated. No further information is available.
16-Dec-2019	UAE; 19BR006042; SP; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 1.50 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Dec-2019	11-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Cacau, a female Shih Tzu of 1.5 years old and 4 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (022/18A, exp date is unknown, topical, btw the shoulder blades) applied by the reporter on 11 Dec 2019 for flea treament. Lack of efficacy is suspected because the pet remains with fleas. FL has been applied only once in the past, on date not informed, with no issue. Environment not treated. No further information is available.
13-Dec-2019	UAE; 19BR006044; MG; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Dec-2019*	Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown number of cats of unknown signalment received FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Dec 2019*), for flea treatment. However, the animals remain with fleas. Environment treated with an unknown product. This is the extent of the information available.
15-Dec-2019	UAE; 19BR006046; SP; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 22 - 25 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Dec-2019	06-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female crossbred dogs of 8 years old (Meg, 22 kg; Sammy, 25 kg) received one pipette of FRONTLINE PLUS DOGS L (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, for the first time, applied by the reporter on 6 Dec 2019 for flea treament. Lack of efficacy is suspected because both dogs remain with fleas. Meg and Sammy are usually bathed once a week. Environment treated with K-Othrine®. No further information is available.
14-Dec-2019	UAE; 19BR006053; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON	Dec-2019	Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 2 female cats of unknown signalment, received FRONTLINE (unsubstantiated) (lot, exp. date, route and administration site), administered by the pet owner on date not provided (Dec 2019* - chosen at random) for unknown reason.

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ED_005739D_00014391-00126

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					According to the reporter, the product was not effective. It is unknown if the issue was solved. Environmental factors are not known. This is the extent of the information available for now.
16-Dec-2019	UAE; 19BR006061; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Dec-2019	12-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Tinho, a male crossbred cat of 3 years old and approx. 5 kg, received one pipette of FRONTLINE SPOT-ON CAT (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, administered by the pet owner on 12 Dec 2019 for flea treatment. Lack of efficacy is suspected because the cat remains with live fleas. Environment treated with Baygon®. No further information is available.
16-Dec-2019	UAE; 19BR006063; RJ; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 3 - 6 kg	6	6	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	06-Dec-2019*	06-Dec-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 6 mixed dogs from 1 to 6 years old and from 3 kg to 6 kg, received FRONTLINE SPRAY 100 ML (005/18A, exp. date unknown; topical, whole body except the head) for the first time, administered by the pet owner on 6 Dec 2019* for flea and tick treatment. Lack of efficacy is suspected because the dogs remained with fleas and ticks; so other 2 applications were performed on 8 Dec 2019* and on 12 Dec 2019*, however the dogs remain with fleas and ticks. The owner also added that fleas and ticks were seen on the environment. Environment treated with unknown product. No further information is available.
16-Dec-2019	UAE; 19BR006066; SP; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 1 - 3 kg	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Nov-2019*	01-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner's mother, 2 male Yorkshire Terrier (Ralf, 1 year old, approx. 1 kg; Joy, 5 years old, 3 kg), received one pipette of FRONTLINE SPOT-ON DOGS S (lot and exp. date unknown; topical, btw the shoulder blades) each, for the first time, administered by the pet owner on 1 Nov 2019* for flea treatment. Lack of efficacy is suspected because the dogs remain with fleas. The owner also added that FRONTLINE TRI-ACT was also used in the past with no issue. Environment partially treated with Butox®. The reporter has a dog that was treated with FL and the same issue occurred (SLOE case reported on BRA-BIAHPV1P-19BR006067). No further information is available.
16-Dec-2019	UAE; 19BR006067; SP; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 2.8 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	01-Nov-2019*	01-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Meg, a female Yorkshire Terrier of 6 years old and 2.8 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, administered by the pet owner on 1 Nov 2019* for flea treatment. Lack of efficacy is suspected because she found 1 flea on Meg after treatment; so today (16 Dec 2019) another FL (019/18A, exp. date unknown) administration was performed as treatment. It is unknown if the dog still has fleas. The owner also added that

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ED_005739D_00014391-00127

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					FRONTLINE TRI-ACT was also used in the past with no issue. Environment partially treated with Butox®. Her son has 2 dogs that were treated with FL and the same issue occurred (SLOE case reported on BRA-BIAHPV1P-19BR006066). No further information is available.
16-Dec-2019	UAE; 19BR006069; PR; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 13 kg	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Oct-2019*	08-Dec-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Vithi, a female medium crossbred dog of 5 years old and 13 kg, received one vial of FRONTLINE PLUS DOG M (FL) (005/18A, unknown exp date, topical, btw the shoulder blades), applied by the reporter on 10 Oct 2019*, for flea control. Lack of efficacy is suspected because the pet got fleas approximately 8 weeks after treatment. Another administration of FL was made on 10 Dec 2019. However, the pet remains with fleas. In addition, Vithi has flea allergy dermatitis. Environment treated with Koral®. FL has been applied every 2 months since date not specified. There is a dog (Batman, a male Yorkshire) that was treated with FRONTLINE PLUS DOG S and a cat that was treated with FRONTLINE PLUS CATS and they have no issue. But the owner mentioned that she applied FRONTLINE (unsubstantiated) on Batman in the past and the product was not effective (SLOE case reported on BRA-BIAHPV1P-19BR006070). No further information is expected.
16-Dec-2019	UAE; 19BR006070; PR; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Jan-2019*	Jan-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Batman, a male Yorkshire of 12 years old and 3 kg, received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Jan 2019*). The product was not effective (details are unknown). The owner also complained that she applied FRONTLINE PLUS DOG M on her other dog on 10 Dec 2019 and it remains with fleas (SLOE case reported on BRA-BIAHPV1P-19BR006069). No further information is available.
09-Dec-2019	UAE; 19BR006074; SP; Brazil	**Species:** Canine **Breed:** Poodle (Standard) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 20 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Nov-2019	14-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Biju, a male Poodle of 6 years old and 20 kg, received one pipette of FRONTLINE PLUS DOGS M (lot and exp. date unknown, topical, btw the shoulder blades), administered by the pet owner on 14 Nov 2019 for flea treatment. Lack of efficacy is suspected because the dog remains with fleas. There are other 2 dogs of the same household treated with FRONTLINE with no issue. Environment treated with Butox®. There are 2 cats and 1 dog of the same household tretated with FRONTLINE facing the same issue (SLOE cases reported on BRA-BIAHPV1P-19BR005899; BRA-BIAHPV1P-19BR005900 and BRA-BIAHPV1P-19BR005901). No further information is available.
17-Dec-2019	UAE; 19BR006106; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 1.5 - 15	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous	01-Nov-2019*	01-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two female dogs (Neguinha, a medium crossbred dog of 4 years old and 15 kg; Minie, a Poodle of 13 years old and 1.5 kg) were treated, for the first time, with FRONTLINE SPRAY (FL) (005/18, unknown exp date, topical, neck and near the tail - low dose), applied by the reporter on 1 Nov 2019*, for flea treatment. However, the owner continued to see fleas on her animals. So, she applied FL again on 14 Dec 2019, but they remain with

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ED_005739D_00014391-00128

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		kg				**Was the product used ok?:** No (Treatment / vaccination program not respected)					ectoparasites. Environment treated with Butox®. No further information is available.
16-Dec-2019	UAE; 19BR006108; SC; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 12 kg*	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	14-Dec-2019	14-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female dogs of less than 13 kg (other signalment is unknown) received one vial of FRONTLINE SPOT-ON DOG M (lot, exp date, route and location are unknown), applied, to each dog, by the reporter on 14 Dec 2019, for tick treatment. However, the animals remain with ticks. Environment was fumigated. There is one more dog in this household that was also treated with FRONTLINE and it has the same issue (SLOE case reported on BRA-BIAHPV1P-19BR006110). No further information is available.
16-Dec-2019	UAE; 19BR006110; SC; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 22 kg*	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	14-Dec-2019	14-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 1 female dog of 22 kg (other signalment is unknown) received one vial of FRONTLINE SPOT-ON DOG L (lot, exp date, route and location are unknown), applied by the reporter on 14 Dec 2019, for tick treatment. However, the animal remains with ticks. Environment was fumigated. There are two more dogs in this household that were also treated with FRONTLINE and they have the same issue (SLOE case reported on BRA-BIAHPV1P-19BR006108). No further information is available.
17-Dec-2019	UAE; 19BR006111; MG; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 2.5 kg	2	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Treatment / vaccination program not respected)	19-Oct-2019	19-Oct-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Cookie, a male Shih Tzu of 3 months old and 2.5 kg, was treated, for the first time, with FRONTLINE SPRAY (lot, exp date, route and location are unknown), applied by the reporter on 19 Oct 2019, for tick treatment. However, the owner continued to see ticks on her pet. So, FL has been applied weekly and ticks are still being found on Nina. Environment treated with deltamethrin. There is a dog in this household that was also treated with FL and it has no issue . No further information is expected.
16-Dec-2019	UAE; 19BR006112; -; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 12 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	16-Dec-2019	16-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female medium crossbred dog of 12 kg (other signalment is unknown) received FRONTLINE SPOT-ON DOGS M (FL) (lot, exp date, route and location are unknown), applied by the reporter on 16 Dec 2019, for flea treatment. However, the pet has flea allergy dermatitis and remains scratching itself. It is unknown if the animal still has fleas. The dog has access to the front yard, where stray dogs are in the area. No further information is available.

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ED_005739D_00014391-00129

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
16-Dec-2019	UAE; 19BR006115; SC; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 3 - 7 kg	5	5	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Jun-2019*	Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown number of cats of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown) applied by the reporter on Jun 2019* for flea treament. According to the reporter, the product has no longer been effective as before because it does not last for 3 months anymore and lately the fleas return to be found on the cats after 30 days of use whenever they visit the house's garden. This is the extent of the information available for now. UPDATE 23 Dec 2019 – The pet owner was contacted and reported that 5 mixed crossbred cats from 12 to 13 years old and 3 to 7 kg received one pipette of FRONTLINE PLUS CATS (FL) (topical, btw the shoulder blades) each, on Jun 2019* for flea treatment. Lack of efficacy is suspected because, according to her, the product's effect does not last for 3 months anymore and lately the fleas return to be found on the cats after 30 days or so of use whenever they visit the house's garden. So, FL started to be applied monthly since date not provided (Sep 2019*) and no more fleas were reported. She added that there are cats in the neighborhood that eventually visit the house. Environment treated with unknown product. No further information is available.
18-Dec-2019	UAE; 19BR006120; MG; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 7.50 Year(s) **Weight:** 9.2 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Dec-2019	12-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Tigrão, a male Yorkshire Terrier of 7.5 years old and 9.2 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 12 Dec 2019 for tick treatment. Lack of efficacy is suspected because the pet remains with ticks . Tigrão is usually bathed every 2 weeks. Environment treated with Butox®. A dog of same household received FRONTLINE simultaneously and LOE is also suspected (see BRA-BIAHPV1P-19BR006121). No further information is available.
18-Dec-2019	UAE; 19BR006121; MG; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 1.50 Year(s) **Weight:** 15.5 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Dec-2019	12-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Boby, a male crossbred dog of approx. 1.5 years old and approx. 15.5 kg, received one pipette of FRONTLINE SPOT-ON DOGS M (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 12 Dec 2019 for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. Boby is usually bathed every 2 weeks. Environment treated with Butox®. A dog of same household received FRONTLINE simultaneously and LOE is also suspected (see BRA-BIAHPV1P-19BR006120). No further information is available.
19-Nov-2019	UAE; 19BR006127; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown	Jan-2018*	Jan-2018*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female dog of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Jan 2018*), for flea control. However, the product was not working anymore for fleas. The owner used to apply FL with no issue in the past (dose frequency is unknown and first aplication was not provided). This is the extent of the information available.

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ED_005739D_00014391-00130

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					
18-Dec-2019	UAE; 19BR006133; SP; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Nov-2019	10-Dec-2019*	12 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Mel, a female dog of unknown signalment received one vial of FRONTLINE PLUS DOG S (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 28 Nov 2019, for flea treatment. The pet was in good health prior to FL and has no history of adverse reactions. After product application, (exact time to onset is unknown), the owner noticed that she is presenting reddening of the skin (back, chin and paws). No vet care was provided. In addition, the owner still sees fleas on her dog (SLOE case reported on BRA-BIAHPV1P-19BR006134). No further information is available.
18-Dec-2019	UAE; 19BR006134; SP; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	28-Nov-2019	28-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female dog of unknown signalment received one vial of FRONTLINE PLUS DOG S (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 28 Nov 2019, for flea treatment. However, the pet remains with fleas and she is scratching herself due to fleas. The pet has daily outdoor access. Environment not treated. In addition, she presented a reaction after product application (SAE case reported on BRA-BIAHPV1P-19BR006133). No further information is expected.
18-Dec-2019	UAE; 19BR006135; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 9.1 - 9.5 kg	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Dec-2019	09-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two dogs of 10 years old (Maia, a femal small crossbred dog og 9.5 kg; Tunica, a female Brazilian Terrier of 9.1 kg) received one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, 'neck area'), applied, to each dog, by the reporter on 9 Dec 2019, for flea treatment. However, the animals remain with fleas. They have no outdoor access. Environment treated with Butox®. FL has been applied since they were puppies (monthly from Nov to May and every 3 months for the rest of the year) and the reporter states that the efficacy has reduced during the last 2 years (no details were provided). One of the dogs presented an 'allergic reaction' after product application (SAE case reported on BRA-BIAHPV1P-19BR006136). No further information is expected.
18-Dec-2019	UAE; 19BR006136; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 9.1 - 9.5 kg	2	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Dec-2019	10-Dec-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two dogs of 10 years old (Maia, a femal small crossbred dog og 9.5 kg; Tunica, a female Brazilian Terrier of 9.1 kg) received one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, 'neck area'), applied, to each dog, by the reporter on 9 Dec 2019, for flea treatment. However, one day post FL application, one of the dogs presented an 'allergic reaction' (it was not informed which dog experienced this issue). FL has been applied monthly since they were puppies. In addition, the owner still sees on her dogs (SLOE case reported on BRA-BIAHPV1P-19BR006135). No further information is expected.
20-Dec-2019	UAE; 19BR006138;	**Species:** Feline **Breed:** Feline	1	1	0	**Product used:** FIPRONIL	17-Dec-2019	20-Dec-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one cat of unknown signalment received one vial

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ED_005739D_00014391-00131

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; Brazil	(unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, applied by the reporter on 17 Dec 2019, for flea treatment. However, 3 days after treatment the reporter still visualizes fleas on her pet. Environmental factors are not known. This is the extent of the information available.
17-Dec-2019	UAE; 19BR006139; RS; Brazil	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 9 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Dec-2019*	03-Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bolinha, a male Poodle of 11 years old and approx. 9 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, applied by the reporter on 3 Dec 2019* for flea treament. Lack of efficacy is suspected because the dog remains with fleas. Environment treated with Colosso®. No further information is available.
18-Dec-2019	UAE; 19BR006140; RJ; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Nov-2019*	Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 3 cats of unknown signalment were treated, for the first time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on Nov 2019*, for flea treatment. However, the number of fleas has increased. They have no outdoor access. This is the extent of the information available.
17-Dec-2019	UAE; 19BR006143; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 40 kg	8	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	14-Dec-2019	14-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 dogs of 40 kg (other signalment is unknown) received FRONTLINE PLUS DOGS L (FL) (lot, exp date, route and location are unknown) applied by the reporter on 14 Dec 2019 for tick treament. Lack of efficacy is suspected because the pets remain with ticks. FL has been applied in the past (dose frequency and 1st adm date not provided) with no issue. The animals live in a farm. Indoor environment factors were not informed. Six other dogs simultaneously received FL with no issue. This is the extent of the information available.
18-Dec-2019	UAE; 19BR006145; SP; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	Dec-2019*	Dec-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 dogs of unknown signalment received, for the first time, one vial of FRONTLINE PLUS (unsubstantiated) (lot, exp date, route and location are unknown), applied, to each dog, by the reporter on date not specified (Dec 2019*), for flea treatment. However, 4 days post product application, the owner found one flea in one of her dogs. Some days later, she found another flea. The current status

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ED_005739D_00014391-00132

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products **Route:** unknown **Was the product used ok?:** Unknown to Company					of the animal is unknown. This is the extent of the information available.
18-Dec-2019	UAE; 19BR006151; SP; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 15.00 Month(s) **Weight:** 2.6 - 4 kg*	5	5	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Dec-2019	03-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 5 cats from 15 months old to 9 years old, weighting 2.6 kg to 4 kg, were treated with one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied to each cat, by the reporter on 3 Dec 2019, for flea treatment. However, the animals remain with fleas. Environment not treated. FL has been administered twice a year since date not specified. No further information is expected.
18-Dec-2019	UAE; 19BR006152; SP; Brazil	**Species:** Canine **Breed:** Dachshund **Sex:** X **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 8.000 - 10 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Treatment / vaccination program not respected)	16-Dec-2019	16-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two Dachshunds (Lucky, male, 7 years old and 10 kg; Scalety, female, 10 years old and 8 kg) received a fractionated dose (0.67 mL) of FRONTLINE PLUS DOG XL (036/18B, exp date, route and location are unknown), applied, on each dog, by the reporter on 16 Dec 2019, for tick treatment. However, the animals remain with ticks. Environment not treated. FL has been applied 3 times a year (dose frequency is unknown) since date not specified. There is one more dog in this household with the same issue (SLOE case reported on BRA-BIAHPV1P-19BR006153) and there is a cat that also received a fractionated dose of FL, but it has no issue (Inquiry reported on BRA-BIAHPV1P-19BR006154). No further information is available.
18-Dec-2019	UAE; 19BR006153; SP; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 17 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Treatment / vaccination program not respected)	16-Dec-2019	16-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Morfeu, a male medium crossbred dog of 4 years old and 17 kg, received a fractionated dose (1.34 mL) of FRONTLINE PLUS DOG XL (FL) (036/18B, exp date, route and location are unknown), applied by the reporter on 16 Dec 2019, for tick treatment. However, the pet remains with ticks. Environment not treated. FL has been applied 3 times a year (dose frequency is unknown) since date not specified. There are two more dogs in this household with the same issue (SLOE case reported on BRA-BIAHPV1P-19BR006152) and there is a cat that also received a fractionated dose of FL, but it has no issue (Inquiry reported on BRA-BIAHPV1P-19BR006154). No further information is available.
16-Dec-2019	UAE; 19BR006157; RS; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products	11-Dec-2019*	11-Dec-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 male crossbred cats (Gruu, 1 year old, 1.5 kg; Bolinho, 6 months old, 900 grams) received FRONTLINE SPRAY 100 ML (FL) (007/19B, April 2021, topical, whole body) applied by the reporter on 11, 12, 13 and 14 Dec 2019 for flea treament. Lack of efficacy is suspected because the cats remain with fleas and they are

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ED_005739D_00014391-00133

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 6.00 Month(s) **Weight:** 0.9 - 1.500 kg*				**Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					scratching themselves due to the ectoparasite infestation. FL has been applied every 30 days with no issue (1st adm date not informed). Environment treated with Gimo®. According to the reporter, the FL cartridge has a different appearance and the product has an abnormal odour (see PRID 558727 reported on GoTrack). has a different appearance No further information is available. 16-JAN-20 QA results received: Investigation completed for FIPRONIL SPRAY Lot# 007/19B, expiry 2021-04-30. Case investigated by France - Toulouse. Final complaint evaluation BIAH QA received a product quality complaint for Spray batch 007/19, on the 20th of December 2019. The complaint description is different odor. After verification, this batch correspond to the bulk batch T021. This is the first complaint regarding this defect for this batch. The complaint sample is not received. Pictures are attached for this case. Not reviewed : the retention sample is stored for identification purposes. Therefore, it is not applicable to this kind of defect. Batch record investigation: Manufacturing date: 27/05/19 - Expiry date: 04/2021 - Manufacturing quantity: 8499 liters. One deviation associated to this batch and unrelated to this defect (OOT : low title in fipronil). This batch is not associated to any change control. One observation associated to this batch related to the deviation. The results of QC testing are conform to specifications. All the parameters verified during the manufacturing of this batch of bulk are conform. Root cause : no root cause established. The product contains a high quantity of isopropyl alcohol,
18-Dec-2019	UAE; 19BR006168; SP; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 9 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Dec-2019*	Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bisteca, a female small crossbred dog of 4 months old and 9 kg*, received, for the first time, one vial of FRONTLINE PLUS DOG S (lot and exp date are unknown, topical btw the shoulder blades), applied by the reporter on date not specified (Dec 2019*), for flea treatment. Fleas are not seen, but the pet is still scratching himself and the reporter believes in the persistence of fleas. Environment not treated. No further information is available.
19-Dec-2019	UAE; 19BR006175; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 5.00 Month(s) **Weight:** 3.8 - 6 kg	5	5	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	30-Nov-2019*	30-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 5 dogs (4 Yorkies and 1 Shih Tzu of mixed sex), from 5 months old to 7 years old, weighting from 3.8 kg to 6 kg, were treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, btw the shoulder blades - off label use), applied by the reporter on 4 Dec 2019*, 11 Dec 2019* and 16 Dec 2019, for flea treatment. However, the animals remain with fleas. Environment treated with Butox®. No further information is available.
19-Dec-2019	UAE; 19BR006176;	**Species:** Canine	1	1	0	**Product used:**	18-Dec-2019	18-Dec-2019	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Thor, a male crossbred of 6 months old and 8 kg, received one pipette of

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ED_005739D_00014391-00134

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	MG; Brazil	**Breed:** Canine Crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 8 kg				FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)					FRONTLINE PLUS DOG M (FL) (lot and exp. date unknown; topical, btw the shoulder blades; off-label use, overdose) for the first time, on 18 Dec 2019 for flea treatment. Thor was in good health prior to FL administration. An unknown time after FL administration, the dog started to present apathy. It is unknown if the animal got recovered. No further information is available.
19-Dec-2019	UAE; 19BR006177; SP; Brazil	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Dec-2019	17-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Belinha, a female Poodle of 11 years old and 8 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 17 Dec 2019, for flea treatment. However, the pet remains with fleas. Environment not treated. FL has been applied once a year since date not specified. The owner applied FL using her finger unprotected (Human exposure reported on BRA-BIAHPV1P-19BR006178). There is one more dog in this household that was treated with another product against fleas, but it is unknown if it has ectoparasite. No further information is available.
19-Dec-2019	UAE; 19BR006187; RJ; Brazil	**Species:** Canine **Breed:** Dachshund **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Dec-2019	14-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Toddy, a male Dachshund of 4 years old and 5 kg*, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, administered by the pet owner on 14 Dec 2019 for flea and tick treatment. Lack of efficacy is suspected because the dog remains with fleas and ticks. Environment not treated. No further information is available.
23-Dec-2019	UAE; 19BR006200; CE; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 1.40 Year(s) **Weight:** 8.9 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Sep-2019*	Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Gil, a female crossbred dog of 1.4 years old and 8.9 kg, received FRONTLINE SPRAY (lot, exp. date, route and administration site are unknown), administered by the pet owner on Sep 2019* for unknown reason. Lack of efficacy is suspected because the dog got infested by ticks. It is unknown if the issue was solved. Environment treated with unknown product. The owner mentioned that NEXGARD was administered and was also not effective (sloe case reported on BRA-BIAHPV1P-19BR006170). No further information is available.
20-Dec-2019	UAE; 19BR006208; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:**	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	13-Dec-2019	13-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 dogs (Benzé, male, crossbred, 6 years old, 32.82 kg*; Diana, female, Border Collie, 8 years old*, 35.6 kg*), received one pipette of FRONTLINE PLUS DOG M (FL) (003/18A, exp. date unknown, topical, btw the shoulder blades; off-label use, low dose) each, for

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ED_005739D_00014391-00135

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** 6.00 Year(s) **Weight:** 32.82 - 35.6 kg				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)					the first time, administered by the pet owner on 13 Dec 2019 for flea treatment. Lack of efficacy is suspected because the dogs remain with fleas. The owner, added that NEXGARD and FRONTLINE SPRAY were administered in the past with no issue. There are other 2 dogs of the same household, also treated with NEXGARD, with no issue. Environment not treated. No further information is available.
20-Dec-2019	UAE; 19BR006213; SP; Brazil	**Species:** Feline **Breed:** Persian (No Further Description) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Month(s) **Weight:** 2 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Dec-2019	10-Dec-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Ragnar, a male Persian of 10 months old and 2 kg, received one vial of FRONTLINE SPOT-ON CAT (FL) (017/18B, unknown exp date, topical, btw the shoulder blades), applied by the reporter on 5 Dec 2019, for flea control. However, some days after product application, the pet got some fleas. Environment treated with Butox®. FL has been applied every 2 months with no issue since date not specified. There is a dog that was treated with FRONTLINE SPOT-ON DOG S and it has the same issue (SLOE case reported on BRA-BIAHPV1P-19BR006214). No further information is expected.
20-Dec-2019	UAE; 19BR006214; SP; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Dec-2019	10-Dec-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Negguts, a male small crossbred dog of 7 years old and 8 kg, received one vial of FRONTLINE SPOT-ON DOGS S (FL) (011/18B, unknown exp date, topical, btw the shoulder blades), applied by the reporter on 5 Dec 2019, for flea control. However, some days after product application, the pet got some fleas. Environment treated with Butox®. FL has been applied every 2 months with no issue since date not specified. There is a cat that was treated with FRONTLINE SPOT-ON CATS and it has the same issue (SLOE case reported on BRA-BIAHPV1P-19BR006213). No further information is expected.
21-Dec-2019	UAE; 19BR006219; RS; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 4 - 8 kg	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	29-Oct-2019*	29-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a female dog of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Dec 2019*), for flea treatment. However, the pet has fleas. This is the extent of the information available. UPDATE 2 JAN 2019 - The owner was contacted and reported that she applied one vial of FRONTLINE SPOT-ON DOGS S (FL) on her two female small crossbred dogs (Guiduka, 5 years old* and 8 kg; Neguinha, 12 years old* and 4 kg). The reporter said that the product was applied to each dog topically in the 'lumbar region' according to the label instructions, on 29 Oct 2019*, for flea treatment. However, the animals remain with fleas. Environment treated with cypermethrin. FL has been applied every 9-12 months with no issue since date not specified. No further information is expected.
23-Dec-2019	UAE; 19BR006227; RS; Brazil	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.50 Year(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	05-Dec-2019	05-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Branca, a female Poodle of 2.5 years old and 6 kg, received, for the first time one vial of FRONTLINE PLUS DOG M (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 5 Dec 2019, for flea treatment. However, the pet remains with fleas. Environment not treated. No further information is expected.

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ED_005739D_00014391-00136

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** No (Overdose)					
23-Dec-2019	UAE; 19BR006234; DF; Brazil	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 9 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Dec-2019*	01-Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Branquinho, a male Poodle of 12 years old* and 9 kg*, was treated, for the first time, with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 1 Dec 2019, for tick treatment. However, the number of ticks has increased. Environment not treated. No further information is available.
23-Dec-2019	UAE; 19BR006239; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 1 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Dec-2019	16-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Toinho, a male crossbred cat of 2 months old and 1 kg, was treated, for the first time, with one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 16 Dec 2019, for flea treatment. However, the pet remains with fleas. Environment treated with Butox®. No further information is expected.
23-Dec-2019	UAE; 19BR006240; SP; Brazil	**Species:** Canine **Breed:** Pug **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 6.5 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	20-Dec-2019	20-Dec-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a female dog of unknown signalment, received FRONTLINE SPRAY 100 ML (lot, exp. date, route and administration site are unknown), administered by the pet owner on Dec 2019* for flea treatment. Lack of efficacy is suspected because the dog remains with fleas . Environmental factors are not known. No further information is available. UPDATE 27 DEC 2019 – The owner was contacted and informed that Nina, a female Pug of 1 year old* and 6.5 kg*, received FRONTLINE SPRAY 100 ML (FL) (topical, whole body) on 20 Dec 2019, for the first time. As the dog remained with fleas and scratching herself, the owner performed 3 administrations on 22 Dec 2019 and other 3 administrations on 26 Dec 2019. The owner informed that Nina was bathed in running water (date not specified) and fleas were seen falling from her body. Environment treated with Butox®. No further information is available for now. UPDATE 3 JAN 2020 – The owner was contacted and informed lot and exp. date (006/18A, Oct 2020). No further information is available
24-Dec-2019	UAE; 19BR006242; -; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 2 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous	17-Dec-2019	17-Dec-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pipoca, a male crossbred cat of 4 years old and 2 kg, was treated, for the first time, with FRONTLINE SPRAY (006/19A, unknown exp date, topical, unknown location), applied by the reporter on 17 Dec 2019 and 21 Dec 2019, for flea treatment. However, the pet remains with fleas. Environment not treated. No further information is expected.

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ED_005739D_00014391-00137

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: No (Treatment / vaccination program not respected)					
23-Dec-2019	UAE; 19BR006244; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Neutered **Age:** 6.00 Month(s) **Weight:** 2 - 4 kg	6	6	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Dec-2019	15-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 6 neutered crossbred cats of mixed sex, from 6 months old to 13 years old, weighting from 2 kg to 4 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied, to each cat, by the reporter on 15 Dec 2019, for flea treatment. However, the animals remained with fleas. So, she administered another product, which was effective and the animals are free of ectoparasites. Environment not treated. FL has been applied every 3 months with no issue since date not specified. The owner also mentioned that FRONTLINE was applied on her dog and the product was not effective (SLOE case reported on BRA-BIAHPV1P-19BR006245). No further information is expected.
23-Dec-2019	UAE; 19BR006245; SP; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Jan-2019*	Jan-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one dog of unknown signalment recieved FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Jan 2019*). However, the product was not effective (details are unknown). The current status of the animal is unknown. Environment not treated. There are 6 cats in this household that were treated with FRONTLINE PLUS CATS and they remain with fleas (SLOE case reported on BRA-BIAHPV1P-19BR006244). No further information is expected.
24-Dec-2019	UAE; 19BR006248; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 47.00 Day(s) **Weight:** 500 gms	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Intentional)	21-Dec-2019	21-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, Emanuel, a male crossbred cat of 47 days old and 500g, received one pipette of FRONTLINE PLUS CATS (lot and exp. date unknown, topical, btw the shoulder blades; off-label use) for the first time, administered by the pet owner on 21 Dec 2019 for flea treatment. Lack of efficacy is suspected because fleas are still being seen on the cat. There are other 5 untreated cats of the same household. Environment not treated. No further information is available.
23-Dec-2019	UAE; 19BR006251; PR; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 40 - 60 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	21-Oct-2019	16-Dec-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 dogs (Urso, male, Rottweiler, 13 years old, 60 kg; Feia, female, crossbred, 10 years old, 40 kg) received one pipette of FRONTLINE PLUS DOGS XL (FL) (lot and exp date unknown, topical, btw the shoulder blades) each, applied by the reporter on 21 Oct 2019 for flea control. Lack of efficacy is suspected because both dogs got fleas approximately 8 weeks after treatment. So, another administration of FL (008/18B, Feb 2020) was made on 21

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ED_005739D_00014391-00138

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** Yes					Dec 2019 and the dogs remain with fleas. FL has been applied every 2 months (1st adm date not provided) with no issue. Environment treated with Butox®. No further information is available.
26-Dec-2019	UAE; 19BR006257; BA; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 3.2 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	22-Dec-2019	22-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Ninna, a female Shih Tzu of 6 months old and 3.2 kg, was treated with FRONTLINE SPRAY (FL) (002/18B, unknown exp date, topical, back and neck - incorrect application), applied by the reporter on 22 Dec 2019, for flea/tick control. However, one flea was found on her pet. Environment treated with cypermethrin. FL has been applied monthly since date not specified. There is another dog in this household with similar issue (SLOE case reported on BRA-BIAHPV1P-19BR006258). No further information is expected.
26-Dec-2019	UAE; 19BR006258; BA; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	22-Dec-2019	22-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Perola, a female Shih Tzu of 6 months old and 3 kg, was treated with FRONTLINE SPRAY (FL) (002/18B, unknown exp date, topical, back and neck - incorrect application), applied by the reporter on 22 Dec 2019, for flea/tick control. However, one tick was found on her pet. Environment treated with cypermethrin. FL has been applied monthly since date not specified. There is another dog in this household with similar issue (SLOE case reported on BRA-BIAHPV1P-19BR006257). No further information is expected.
26-Dec-2019	UAE; 19BR006260; SP; Brazil	**Species:** Canine **Breed:** Retriever Labrador **Sex:** X **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 41 - 45 kg	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Dec-2019	22-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two dogs (Nina, a female Labrador of 5 years old and 41 kg*; Zé, a male Labrador of 5 years old and 45 kg) were treated, for the first time, with one vial of FRONTLINE SPOT-ON DOG XL (lot and exp date are unknown, topical, btw the shoulder blades), applied, to each dog, by the reporter on 22 Dec 2019, for flea treatment. However, the animals remain with fleas. Environment treated with an unknown product. No further information is expected.
26-Dec-2019	UAE; 19BR006266; DF; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 4 kg	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	19-Nov-2019	19-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mia, a female crossbred dog of 1 year old and 4 kg, received one pipette of FRONTLINE PLUS DOG M (FL) (013/18A, exp. date unknown, topical, unknown administration site; off-label use, overdose), administered by the pet owner on 19 Nov 2019 for flea and tick control. Lack of efficacy is suspected because fleas and ticks are being seen on the dog. FRONTLINE has been administered every 3 months (first administration date not informed) with no issue. There are other 2 dogs of the same

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ED_005739D_00014391-00139

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** No (Overdose)					household treated with FRONTLINE with no issue. Environment treated every 4 months (last treatment date not informed). No further information is available.
25-Dec-2019	UAE; 19BR006267; RJ; Brazil	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 9 kg*	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Dec-2019	23-Dec-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 4 dogs of unknown signalment received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied, to each dog, by the reporter on 20 Dec 2019*, for flea/tick treatment. One day after product application, no ectoparasite was seen. However, some days later, the owner noticed fleas and ticks on her animals. There are 3 other dogs in this household that were treated with FRONTLINE PLUS DOG M and they have the same issue (SLOE case reported on BRA-BIAHPV1P-19BR006268). The owner also mentioned that she applied FRONTLINE SPRAY in the past and it was not effective (SLOE case reported on BRA-BIAHPV1P-19BR006269). No further information is expected. UPDATE 27 DEC 2019 - The owner was contacted and reported that 4 small crossbred dogs of 1 year old to 19 years old and weighting less than 10 kg received FL on 21 Dec 2019. However, the animals remain with ticks. They have no outdoor access. Environment not treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). There are some cats in this household and they have no issue, but it is unknown if they were treated. No further information is available.
25-Dec-2019	UAE; 19BR006268; RJ; Brazil	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** X **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 15 kg	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Dec-2019	23-Dec-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 3 dogs of unknown signalment received one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied, to each dog, by the reporter on 20 Dec 2019*, for flea/tick treatment. One day after product application, no ectoparasite was seen. However, some days later, the owner noticed fleas and ticks on her animals. There are 4 other dogs in this household that were treated with FRONTLINE PLUS DOG S and they have the same issue (SLOE case reported on BRA-BIAHPV1P-19BR006267). The owner also mentioned that she applied FRONTLINE SPRAY in the past and it was not effective (SLOE case reported on BRA-BIAHPV1P-19BR006269). No further information is expected. UPDATE 27 DEC 2019 - The owner was contacted and reported that her 3 medium crossbred dogs of 5 years old to 15 years old and weighting 15 kg* received FL on 21 Dec 2019. However, the animals remain with ticks. They have no outdoor access. Environment not treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). There are some cats in this household and they have no issue, but it is unknown if they were treated. No further information is available.
25-Dec-2019	UAE; 19BR006269; RJ; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	3	3	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown	Jan-2019*	Jan-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of dogs of unknown signalment were treated with FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Jan 2019*). However, the product was not effective (details were not provided). The owner also complained that FRONTLINE PLUS DOG S and FRONTLINE PLUS DOG M

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ED_005739D_00014391-00140

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				**Was the product used ok?:** Unknown to Company					did not work on her dogs (SLOE cases reported on BRA-BIAHPV1P-19BR006267 and BRA-BIAHPV1P-19BR006268). No further information is expected.
25-Dec-2019	UAE; 19BR006270; RJ; Brazil	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 10 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	22-Oct-2019*	22-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a Poodle of unknown signalment received one vial of FRONTLINE PLUS DOG S (FL) (022/18B, May 2020, route and location are unknown), applied by the reporter on Oct 2019 and Nov 2019, for tick treatment. However, the pet remains with ticks. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). This is the extent of the information available. UPDATE 27 DEC 2019 – The owner was contacted and informed that Samly, a male Poodle of 2 years old and 10 kg*, received FL on 22 Oct 2019* and 22 Nov 2019*. The dog remains with ticks. The owner added that there are many stray dogs on the neighborhood. The environment has been treated 3 times a week with Butox® and an unknown insecticide powder. The owner also mentioned an AE involving a FRONTLINE administration on Samly (SAE case reported on BRA-BIAHPV1P-19BR006284).
23-Dec-2019	UAE; 19BR006277; CE; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 1.1 - 2.9 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	Nov-2019*	Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, a female dog of other signalment unknown, received FRONTLINE SPRAY (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on Nov 2019* for unknown reason. According to the reporter, the product was not effective. So on Dec 2019* another bottle of FL was purchased and another administration was performed and the same issue occurred. Environmental factors are not known. This is the extent of the information available for now. UPDATE 2 JAN 2020 – The owner was contacted and informed that 2 female dogs (Mel, Pinscher, 3 years old, 1.1 kg; Pretinha, crossbred, 6 years old and 2.9 kg), received FRONTLINE SPRAY 100 ML (002/18; topical, parts of the body) on various dates (last adm on 24 Dec 2019) for tick treatment. The dogs remain with ticks. The dogs have outdoor access and are bathed monthly at a retail shop. Environment partially treated with unknown product. No further information is available.
27-Dec-2019	UAE; 19BR006284; RJ; Brazil	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 10 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Jun-2019*	Jun-2019*	N/A	D-D	Suspected Adverse Event: As reported by the pet owner, Samly, a male Poodle of 2 years old and 10 kg*, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown), on Jun 2019* for unknown reason. An unknown time after FL administration, Samly presented bloody urine. It was a single episode and the dog recovered spontaneously. The owner also complained of lack of efficacy involving FRONTLINE (SLOE case reported on BRA-BIAHPV1P-19BR006270). No further information is available.
23-Dec-2019	UAE; 19BR006288; RJ; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** X **Sex qualifier:**	8	8	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other	25-Nov-2019	25-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 8 mixed crossbred dog from 1.5 years old to 6 years old and from 5 kg to 12 kg, received FRONTLINE SPRAY 250 ML (FL) (003/18, exp. date unknown; topical, whole body), administered by the pet owner on 28 Nov 2019 for tick treatment. According to the reporter,

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ED_005739D_00014391-00141

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** 1.50 Year(s) **Weight:** 5 - 12 kg				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					the product was not effective and lack of efficacy is suspected because the dogs remain with ticks. FL has been administered every 9 months (first administration date not provided) with no issue. Environment treated every 4 months (last treatment is unknown). No further information is available for now.
26-Dec-2019	UAE; 19BR006292; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 10.00 Month(s) **Weight:** 3 - 6 kg	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Dec-2019*	16-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 crossbred cats (Toddy, male, 5 years old*, 6 kg*; Tica, female, 2.5 years old, 3 kg; Theo, male, 10 months old, 3 kg), received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp. date unknown; topical, btw the shoulder blades) each, for the first time, administered by the pet owner on 16 Dec 2019* for flea treatment. Lack of efficacy is suspected because the cats remain with fleas and are scratching themselves due to the infestation. Environment not treated. No further information is available for now.
27-Dec-2019	UAE; 19BR006294; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 700 - 800 gms	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	24-Dec-2019	24-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female crossbred cats of 4 months old and from 700 grams to 800 grams, received one pipette of FRONTLINE PLUS CATS (FL) (018/18A, exp. date unknown; topical, btw the shoulder blades) each, for the first time, administered by the pet owner on 24 Dec 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. The owner added that fleas actually increased in quantity after the product administration. Environment treated with Triatox®. There are other 3 dogs of the same household treated with FRONTLINE facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR006295). No further information is available for now.
27-Dec-2019	UAE; 19BR006295; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 1.8 - 4.2 kg	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	24-Dec-2019	24-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 female dogs (Lala, Pinscher, 5 years old, 1.8 kg; Lilica, Pinscher, 2 years old, 2.8 kg; Mel, Pug, 3.8 years old, 4.2 kg), received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknown; topical, btw the shoulder blades) each, for the first time, administered by the pet owner on 24 Dec 2019 for flea treatment. Lack of efficacy is suspected because the dogs remain with fleas . The owner added that fleas actually increased in quantity after the product administration. Environment treated with Triatox®. There are other 2 cats of the same household treated with FRONTLINE facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR006294).No further information is available for now.
27-Dec-2019	UAE; 19BR006301; RJ; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 3 - 6.5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	17-Dec-2019	17-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female crossbred cats of 5 years old and from 3 kg to 6.5 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp. date unknown; topical, btw the shoulder blades) each, for the first time, administered by the pet owner on 17 Dec 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with fleas. The owner added that fleas actually increased in quantity after the product administration. Environment not treated. One of the cats experienced an SAE after product administration (see case BRA-BIAHPV1P-19BR006302). No further information is

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ED_005739D_00014391-00142

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					available for now.
27-Dec-2019	UAE; 19BR006302; RJ; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 6.5 kg	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Dec-2019	17-Dec-2019	0 Day(s)	D-C	Suspected Adverse Event: As reported by the pet owner, Agata, a female crossbred cat of 5 years old and 6.5 kg, received one pipette of FRONTLINE PLUS CATS (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, administered by the pet owner on 17 Dec 2019 for flea treatment. The health status of the animal prior to the product administration is unknown. According to the reporter, an unknown time after product administration, Agata was not eating, not drinking water and presented apathy. The owner also informed that the cat lost weight. Agata recovered spontaneously. There is another cat of the same household treated with FL with no issue. Althought, the owner complained of lack of efficacy (see case BRA-BIAHPV1P-19BR006301). No further information is available. UPDATE 2 JAN 2020 – The owner was contacted and informed that, Agata experienced vomiting, anorexia and weigh loss. On 21 Dec 2019, the cat recovered spontaneously. The owner added that may have a possibility of Agata have had oral contact with the FRONTLINE applied in the contactant animal. No further information is available.
27-Dec-2019	UAE; 19BR006309; -; Brazil	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 30 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	25-Dec-2019	25-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a female Labrador of 13 years old and 30 kg, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown) administered by the pet owner on 25 Dec 2019 for unknown reason. Lack of efficacy is suspected because the dog is scratching herself. Environmental factors are not known. No further information is available for now.
27-Dec-2019	UAE; 19BR006312; SP; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 3 - 5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Dec-2019	17-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female crossbred cats (Michele, 1.6 years old, 5 kg; Rita, 6 months old, 3 kg) received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, applied by the reporter on 17 Dec 2019 for flea treament. Lack of efficacy is suspected because both cats remain with fleas. FL has been applied in the past (dose frequency and 1st adm date not provided) with no issue. There are untreated dogs living in the same household. Environment treated with Butox®. No further information is available.
28-Dec-2019	UAE; 19BR006313; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown	Dec-2019*	Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, an unknown number of dogs of unknown signalment, received FRONTLINE SPRAY (FL) (lot, exp. date, route and administration site are unknown) administered by the pet owner on Dec 2019* for flea treatment. According to the reporter, the product was no effective. So another administration was performed; however it was also not effective. Environmental factors are not

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ED_005739D_00014391-00143

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				**Was the product used ok?:** Unknown to Company					known. There are other cats of the same household also treated with FL and the same issue occurred (SLOE case reported on BRA-BIAHPV1P-19BR006314). No further information is available for now.
28-Dec-2019	UAE; 19BR006314; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Dec-2019*	Dec-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, an unknown number of cats of unknown signalment, received FRONTLINE SPRAY (FL) (lot, exp. date, route and administration site are unknown) administered by the pet owner on Dec 2019* for flea treatment. According to the reporter, the product was no effective. So another administration was performed; however it was also not effective. Environmental factors are not known. There are other dogs of the same household also treated with FL and the same issue occurred (SLOE case reported on BRA-BIAHPV1P-19BR006313). No further information is available for now.
28-Dec-2019	UAE; 19BR006316; SP; Brazil	**Species:** Feline **Breed:** Siamese **Sex:** F **Sex qualifier:** Unknown **Age:** 52.00 Day(s) **Weight:** 700 gms	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	18-Dec-2019	18-Dec-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a female cat of 2 months old and other signalment unknown, received FRONTLINE SPRAY (FL) (lot, exp. date, route and administration site are unknown) administered by the pet owner on 1 Dec 2019* for flea treatment. According to the reporter, the product was no effective. So another two administrations were performed; however were also not effective. Environmental factors are not known. No further information is available for now. UPDATE 2 JAN 2020 – The owner contacted BIAH and informed that Babi, a female Siamese cat of 52 days old and 700 grams, received FRONTLINE SPRAY 100 ML (006/19, exp. date unknown; topical, whole body) on 18 Dec 2019, for the first time. As fleas remained to be seen, another 3 administrations were performed on 22 Dec 2019, 28 Dec 2019 and on 29 Dec 2019. The cat remains with fleas. Environment has been treated with Butox®. No further information is available.
28-Dec-2019	UAE; 19BR006317; -; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Dec-2019*	01-Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a cat of unknown signalment, received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown) administered by the pet owner on 1 Dec 2019* for flea treatment. According to the reporter, the product was no effective and lack of efficacy is suspected because the cat remains with fleas and is scratching itself due to the infestation. Environmental factors are not known. No further information is available for now.
09-Dec-2019	UAE; 19BR006321; SP; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 3.3 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Dec-2019	07-Dec-2019	2 Day(s)	D-C	Suspected Adverse Event: As reported by the pet owner via retailer, Zoe, a female Shih Tzu of 7 months old and 3.3 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (lot and exp. date unknown; topical, btw the shoulder blades) for the first time, administered by the pet owner on 5 Dec 2019 for flea treatment. On 7 Dec 2019, in the morning, the dog started to experience vomiting, bloody diarrhea, anorexia, apathy and hypersalivation. The owner informed that there is another dog of the same household, also treated with FRONTLINE (unsubstantiated) with no issue, and may have possibility that Zoe have had oral contact with the product. The clinical signs are

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ED_005739D_00014391-00144

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											ongoing. Zoe was in good health prior to FL administration and there no history of AE to other products. No further information is available.
28-Dec-2019	UAE; 19BR006323; SP; Brazil	**Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 3.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	19-Dec-2019	19-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a dog of unknown signalment, received FRONTLINE PLUS DOG S (FL) (lot, exp. date, route and administration site are unknown) administered by the pet owner on 19 Dec 2019 for flea treatment. Lack of efficacy is suspected because the dog remains with fleas. Environmental factors are not known. No further information is available for now. UPDATE 31 DEC 2019 – The owner was contacted and informed that Lua, a female Lhasa Apso of 7 months old and approx 3.5 kg*, received one pipette of FL (topical, unknown administration site) for the first time. As the dog remained with fleas, the owner sheared her and a collar for fleas is being worn. According to the reporter, fleas decreased in quantity; however a few are still being seen. Environment treated with Amitraz and Butox®.
28-Dec-2019	UAE; 19BR006324; -; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	05-Dec-2019*	25-Dec-2019*	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, a female dog of other signalment unknown, received FRONTLINE (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown) administered by the pet owner on 5 Dec 2019* for flea treatment. Lack of efficacy is suspected because on 25 Dec 2019* fleas returned to be seen on the dog. Environmental factors are not known. No further information is available for now.
29-Dec-2019	UAE; 19BR006326; SP; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 3.3 - 7.5 kg*	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	19-Nov-2019	19-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via email, 2 female dogs of 4 years old and less than 10 kg, received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp. date, route and administration site are unknown) administered by the pet owner on Nov 2019* for flea treatment. Lack of efficacy is suspected because the dogs remained with fleas. So on Dec 2019* another administration was performed; however fleas and flea feces are still being seen on the dogs. The dogs are regularly bathed with ectoparasiticide shampoo. FRONTLINE was administered in the past (dose frequency and first administration are unknown) with no issue. Environmental factors are not known. No further information is available for now. UPDATE 7 JAN 2020 – The owner contacted BIAH and informed that 2 female crossbred dog from 3.3 kg to 7.5 kg, received one pipette of FRONTLINE PLUS DOG S (topical, btw the shoulder blades) each, on 19 Nov 2019 for flea control. As the dogs remained with fleas, another administration was performed on 15 Dec 2019; however it was also not effective. FRONTLINE has been administered monthly (first administration date unknown) with no issue. Environment not treated. No further information is available for now.
30-Dec-2019	UAE; 19BR006335; SP; Brazil	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Pregnant	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	11-Dec-2019	11-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Angel, a pregnant female Shih Tzu of 2 years* and 5 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknown, topical, from base of skull to btw the shoulder blades) administered by pet owner on 11 Dec 2019 for tick treatment. Lack

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ED_005739D_00014391-00145

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 2.00 Year(s) **Weight:** 5 kg				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					of efficacy is suspected because the dog remains with ticks . The owner mentioned that ticks are also being seen on the environment. FL has been administered every 45 days (first administration date not provided) with no issue. Environment not treated. There is another dog of the same household treated with NEXGARD facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR006334). No further information is available for now.
27-Dec-2019	UAE; 19BR006341; SP; Brazil	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 8.7 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Nov-2019	28-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female crossbred dog of 6 years old and 8.7 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknonw, topical, btw the shoulder blades) administered by pet owner on 28 Nov 2019 for flea treatment. Lack of efficacy is suspected because the dog remains with fleas. FL has been administered every 3 months (first administration date not provided) with no issue. Environment treated with unknown product. There is another dog of the same household that faced similar issue after FRONTLINE (SLOE case reported on BRA-BIAHPV1P-19BR006342). No further information is available for now.
27-Dec-2019	UAE; 19BR006342; SP; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 9 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	28-Nov-2019	28-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a dog of less than 10 kg received 1 vial of FRONTLINE PLUS DOGS (FL) (unsubstantiated) (lot and exp. date unknown, topical, btw the shoulder blades) administered by pet owner on 28 Nov 2019 for flea treatment. Lack of efficacy is suspected because the dog remained with fleas. The animal recovered spontaneously on date not informed (20 Dec 2019*). FL has been administered every 3 months (first administration date not provided) with no issue. Environment treated with unknown product. There is another dog of the same household treated with FRONTLINE facing the same issue (SLOE case reported on BRA-BIAHPV1P-19BR006341). No further information is available for now.
30-Dec-2019	UAE; 19BR006344; -; Brazil	**Species:** Feline **Breed:** Feline crossbred **Sex:** X **Sex qualifier:** Unknown **Age:** 1.30 Year(s) **Weight:** 4.1 - 4.5 kg	5	5	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL SPRAY; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Nov-2019	22-Nov-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 5 mixed crossbred cats from 1.3 years old to 15 years old and from 4.1 kg to 4.5 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp. date unknown; topical, btw the shoulder blades) each, administered by pet owner on 22 Nov 2019 for flea treatment. Lack of efficacy is suspected because the cats remained with fleas. So on 6 Dec 2019*, FRONTLINE SPRAY 100 ML (002/18A, exp. date unknown; whole body except head and legs) was administered; however the cats remain infested. Environment treated with K-Othrine® and Talfon®. No further information is available for now.
30-Dec-2019	UAE; 19BR006358; MG; Brazil	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	25-Nov-2019	28-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Penélope, a female Yorkshire of 14 months old and 3.5 kg, received, for the first time, one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 25 Nov 2019, for flea/tick control. Some days after product application, the pet got ticks.

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ED_005739D_00014391-00146

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 14.00 Month(s) **Weight:** 3.5 kg				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					Environment not treated. No further information is expected.
11-Dec-2019	UAE; 19BR006377; RS; Brazil	**Species:** Canine **Breed:** Poodle (Standard) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 9 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Dec-2019	02-Dec-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bolinha, a male Poodle of 10 years old and 9 kg, received one pipette of FRONTLINE PLUS DOG S (FL) (lot and exp. date unknown; topical, btw the shoulder blades), administered by the pet owner on 2 Dec 2019 for tick treatment. According to the reporter, the product was not effective and lack of efficacy is suspected because the dog remains with ticks. FRONTLINE has been administered every 3 months (first administration date unknown) with no issue. Environment treated with Colosso®. No further information is available for now.
10-Dec-2019	UAE; 19BR006380; SP; Brazil	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** 2 - 15 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	10-Nov-2019*	10-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 2 dogs (Estela, female, crossbred, 15 kg; Rafael, Pomeranian, 2 kg), received FRONTLINE SPRAY 100 ML (FL) (006/19, exp. date unknown; topical, parts of the body), administered by the pet owner on 10 Nov 2019* for flea treatment. Lack of efficacy is suspected because the dogs remained with fleas. Rafael also presented one tick on date not informed. So, Bravecto® was administered and no more ectoparasites were reported. The dogs have daily outdoor access. FRONTLINE was administered in the past (dose frequency and first administration date unknown) with no issue. Environment treated every 15 days with Butox®. The reported mentioned another 2 SLOE cases involving FRONTLINE (see cases reported on BRA-BIAHPV1P-19BR006381 and BRA-BIAHPV1P-19BR006382). No further information is available.
10-Dec-2019	UAE; 19BR006381; SP; Brazil	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner's related person, 4 dogs* of unknown signalment, received FRONTLINE SPRAY (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on Oct 2019* for unknown reason. According to the reporter, the product was not effective. It is unknown if the issue was solved. Environmental factors are not known. The reported mentioned another 2 SLOE cases involving FRONTLINE (see cases reported on BRA-BIAHPV1P-19BR006380 and BRA-BIAHPV1P-19BR006382). No further information is available.
10-Dec-2019	UAE; 19BR006382; SP; Brazil	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used**	Oct-2019*	Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner's related person, 3 cats* of unknown signalment, received FRONTLINE SPRAY (FL) (lot, exp. date, route and administration site are unknown), administered by the pet owner on Oct 2019* for unknown reason. According to the reporter, the product was not effective. It is unknown if the issue was solved. Environmental factors are not known. The reported mentioned another 2 SLOE cases involving FRONTLINE (see cases reported on BRA-BIAHPV1P-19BR006380 and

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ED_005739D_00014391-00147

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					BRA-BIAHPV1P-19BR006381). No further information is available.
13-Dec-2019	UAE; 19CL000039; Santiago, Chile; Chile	**Species:** Feline **Breed:** - **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Month(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	09-Dec-2019	09-Dec-2019	0 Day(s)	D-D	On 12 DEC 2019 owner reported lack of efficacy: A 9-month old cat ("Nara", 3 kg, neutered female) was treated with FRONTLINE SPRAY (100 mL) (batch unknown, expiry date unknown) topically administered by owner on 09 DEC 2019. After product administration, the owner saw no effect, the cat still has fleas to date (12 DEC 2019).
13-Dec-2019	UAE; 19CL000040; -; Chile	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** 10 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** - **Was the product used ok?:** Unknown to Company	09-Dec-2019	09-Dec-2019	0 Day(s)	D-D	On 12 DEC 2019 owner reported lack of efficacy: A 4-year old crossbreed ("León", 10 kg, intact male, in good health status) was treated with FRONTLINE SPRAY (100 mL) (batch unknown, expiry date unknown) topically administered by owner on 09 DEC 2019. The dosage is unknown, the owner stated that it was applied until the dog was wet.After product administration, the owner saw no effect, the dog still has fleas and ticks to date (12 DEC 2019). The owner applied the product until dog was quite wet.The owner stated that the product does not work.
16-Dec-2019	UAE; 19CL000041; Santiago, Chile; Chile	**Species:** Canine **Breed:** Canine Crossbred **Sex:** X **Sex qualifier:** Neutered **Age:** - **Weight:** Unknown	7	7	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	06-Dec-2019	06-Dec-2019	N/A	D-D	On 13 DEC 2019 owner reported lack of efficacy: A group of 7 dogs (mixed sex) was treated with FRONTLINE SPRAY (250 mL) (batch unknown, expiry date unknown) topically administered by owner on 06 DEC 2019. After product administration, the owner saw no effect, the dogs still have fleas and ticks (13 DEC 2019). The owner stated that the product does not work.
19-Dec-2019	UAE; 19CL000043; San Fernando, Chile; Chile	**Species:** Canine **Breed:** - **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	05-Dec-2019	06-Dec-2019	N/A	D-D	On 1ST DECEMBER 2019 owner reported adverse event: name unknown, age unknown, weight unknown, canine, breed unknown, reproductive status unknown, received FRONTLINE SPRAY, batch unknown, expiry date unknown, route topical, location unknown, dose unknown), administered by owner on the DECEMBER 2019, one day after product administration one dog animal experienced skin erythema and other dog experienced alopecia. No Analysis/tests were performed. The animal were not treated. Update on 20 DECEMBER 2019 owner states dogs have improved over the days, no erythema is visible and no new areas with alopecia are seen.
02-Oct-2019	UAE; 19DE000841; -; Germany	**Species:** Canine **Breed:** Retriever Labrador **Sex:** U **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other	Sep-2019*	Sep-2019*	0 Day(s)	D-C	As reported by a pharmacist a Labrador dog (no further details) was treated with Frontline Spray (batch R03802A, exp. date Dec 2019, no further details) due to an unknown reason. An unspecified time later the dog showed staggering, neurological problems, insomnia, and restlessness. No further information

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ED_005739D_00014391-00148

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** - **Weight:** Unknown				products **Route:** unknown **Was the product used ok?:** Unknown to Company					availabe.
27-Oct-2019	UAE; 19DE000913; -; Germany	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	0 Day(s)	D-D	SLEE: As reported by the animal owner a dog (no more details available) was treated with FRONTLINE COMBO SPOT ON DOGS XL (no more details available) by the animal owner at some unspecied date (best guess: October 2019) due to flea/tick treatment. 2 days after the administration of FRONTLINE COMBO there were still living fleas visible. No further details available.
25-Oct-2019	UAE; 19DE000916; -; Germany	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	24-Oct-2019	24-Oct-2019	0 Day(s)	D-D	As reported by the animal owner a dog (no further details) was treated with FRONTLINE SPOT-ON (no further details, 'Frontline Spot-on H 20' set as best guess) on 24 Oct 2019 topically in the neck. In the night following the teatment the dog showed pruritus. No further information available.
07-Nov-2019	UAE; 19DE000942; -; Germany	**Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 5.500 kg*	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	07-Nov-2019	07-Nov-2019	few hours	D-D	As reported by the animal owner a European cat, neutered male, 4 years old, about 5.5 kg body weight in unknown general condition was treated with FRONTLINE SPOT-ON K (no more details available) by the animal owner due to flea/tick treatment. A few hours after the treatment, the cat started to behave strangely: The animal seemed to be tired and ´ had problems finding a suitable place to lie down´. Whenever the cat lied down it started to meow as if it were in pain (together coded as behavioral disorder and vocalisation), this condition continued into the night. On 8 November 2019, the cat is recovered. No more details available.
07-Nov-2019	UAE; 19DE000954; -; Germany	**Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 4 kg*	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	Aug-2019	Aug-2019*	0 Day(s)	D-C	As reported by the animal owner a cat, European, female neutered, 5 years old, 4 kg body weight approx. in good condition was treated with FRONTLINE SPOT-ON K (topical in the neck, 1 dose. No more details available) by the animal owner in August 2019, due to flea/tick prophylaxis. 2 days later, the cat presented a rash (crusts) on the entire body, especially in the abdominal area. The cat recovered after 1-2 weeks (reported recovery date 11 Nov 2019- contradictury data). There was no flea infestation at that time. According to the animal owner, the cat presented the same symptoms 1 year ago. No more information available. The animal owner showed similar symptoms and is reported in the linked case DEU-BIAHPV1P-19DE000953.

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ED_005739D_00014391-00149

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
11-Nov-2019	UAE; 19DE000960; -; Germany	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	N/A	D-D	SLEE: As reported by the animal owner a cat (no more details available) was treated with FRONTLINE SPOT-ON K by the animal owner several times (unspecified period of time, estimated date: October 2019) due to flea/tick control. According to the animal owner the cat still has fleas despite treatment. No more details available.
12-Nov-2019	UAE; 19DE000961; -; Germany	**Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 2.4 kg	2	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Nov-2019	11-Nov-2019	0 Day(s)	D-D	As reported by the animal owner a cat (European, female intact, 6 months, 2.4 kg body weight in good condition) was treated with FRONTLINE SPOT-ON K (topical/cutaneous route, neck, 1 single dose, batch number T20110AW, exp. date 12/21) by the animal owner on 11 November 2019 due to flea/tick treatment. Some time after receiving the treatment, the cat began to salivate massively and once vomited the stomach content. Thereafter, the animal owner washed the cat's paws and mouth. After that, all the symptoms stopped immediately. There is another male cat living in the same household which was also treated with Frontline Spot-on K (1 dose) with no symtoms. No more details available.
26-Nov-2019	UAE; 19DE001006; -; Germany	**Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 4.1 kg	1	1	1	**Product used:** FIPRONIL SPRAY **Other products used:** Metacam meloxicam 5 mg/ml injection dog cat; Synulox RTU; Ketamin; Sedoxil; Isofluran; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	26-Nov-2019	26-Nov-2019	0 Day(s)	D-A	As reported by the attending vet a cat, European, female neutered, 5 years old, 4.1 kg body weight in fair condition underwent surgery due to a mammary tumor on 26 Nov 2019 and was therefore anaesthetized with Ketamine (no further details) and Sedoxil (no further details) as induction. After intubation the cat received Isoflurane (no further details) per inhalation. Routinely, the cat received METACAM 5 mg/ml solution for injection for dogs and cats (s.c., 0.3 mg/kg, batch 1120812A-09, exp. date 01/2021, no further details) due to pain after surgery, Synulox RTU due to infection prophylaxis (s. c., according to package leaflet, batch 91912602, exp. date: 02/2021, no further details), and Ringer-Laktat (i.v. infusion, no further details), all by the attending vet. At 11:30 a.m. (beginning of head lift, during the anesthetic recovery period), the cat was treated with FRONTLINE SPRAY (topical/cutaneous with gloves, sprayed all over its body except the abdominal area until the fur was wet, batch R03305A, exp. date 08/2020, no further details) by the attending vet, due to high-grade flea infestation. Shortly after, the cat showed cramps in the legs and opisthotonos, followed by respiratory arrest. Around 04:30 p.m., the cat did still not breathe spontaneously and needed artificial respiration. The cramps disappeared after about 15-30 minutes and the cat did show almost no reflexes. A little bit later the reflexes to stimulus in the inter-toe area increased but still no eyelid reflexes. The cat received Dopram twice (no further details). After 6.5 hours with artificial breathing the cat was transported to another clinic. Although the cat was continuously ventilated the cat did not survive the transport. No further information available.
02-Dec-2019	UAE; 19DE001036; -; Germany	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products	01-Nov-2019*	30-Nov-2019*	29 Day(s)	D-D	SLEE: As reported by the attending vet a dog (10 kg body weight, in good general condition) was treated once topically with 1 dose of FRONTLINE SPOT ON M /batch no R21312CX, expiry date Jul 2020) by the animal owner beginning of Nov 2019 due to prophylaxis. Mid Nov 2019 another dog from Romania with intense flea infestation was brought to this household. End Nov 2019 the initially Frontline -treated dog showed also flea infestation. The

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ED_005739D_00014391-00150

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		Age: - **Weight:** 10 kg				**Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					environment was vaccumed. No more details.
07-Dec-2019	UAE; 19DE001050; -; Germany	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 30 kg	3	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	23-Nov-2019*	24-Nov-2019*	1 Day(s)	D-D	SLEE and AE: As reported by the animal owner a neutered male Golden Retriever dog (30 kg bodyweight, in good condition, no further details) was treated topically in the neck with 1 dose of FRONTLINE SPOT-ON H 40 (no further details) by the animal owner about 2 weeks ago due to massive flea infestation. She also treated the other 2 dogs (no further details) in the same household but not the 2 cats. All blankets were washed and a not further specified spray used as enviroment treatment. The Golden Retriever showed intense pruritus and despite the treatment with Frontline multiple fleas but there were no flea excrements. On the other dogs there were no fleas. No further information available. MAH comment: this case is classified as both 'SLEE' and 'Adverse Reaction', but due to a limitation of the database it might be that only the highest hierarchical product problems type, which is 'Adverse Reaction', has been transmitted.
02-Dec-2019	UAE; 19DE001055; -; Germany	**Species:** Feline **Breed:** Maine Coon Cat **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	27-Nov-2019	28-Nov-2019	N/A	D-D	SLEE: As reported by the animal owner a Maine Coon cat (no further details) was treated topically with 1 dose of FRONTLINE SPOT-ON K (no further details) by the owner on 27 Nov 2019 due to massive flea infestation. Since she found fleas on the cat and herself, she treated the cat again with 1 dose of Frontline Spot-on K on 06 Dec 2019. She still can find fleas on the cat but the fleas now seem to be slower than usual. There was some form of environment treatment (no further details). No further information available.
07-Dec-2019	UAE; 19DE001058; -; Germany	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Treatment / vaccination program not respected)	Dec-2019*	Dec-2019*	0 Day(s)	D-D	As reported by an animal owner an unknown dog has been treated 3 times in the last 4 weeks with unknown FRONTLINE. However, ´the dog is still itching and it doesn´t work despite treatment of the environment´. No more details. Coded as SLEE by best guess.
31-Dec-2019	UAE; 19DE001138; -; Germany	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:**	3	3	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other	Dec-2019*	Dec-2019*	0 Day(s)	D-D	As reported by the animal owner 3 large dogs (no further details) were treated with FRONTLINE ('FRONTLINE SPOT-ON H 40' set as best guess, no further details). Dec 2019 as time of administration set as best guess. The owner complained about the missing efficacy. No further information available. Same reporter

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ED_005739D_00014391-00151

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** - **Weight:** Large dogs				products **Route:** unknown **Was the product used ok?:** Unknown to Company					as DEU-BIAHPV1P-19DE001139, cases are linked.
31-Dec-2019	UAE; 19DE001139; -; Germany	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	6	6	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Dec-2019*	Dec-2019*	0 Day(s)	D-D	As reported by the animal owner 6 cats (no further details) were treated with FRONTLINE ('FRONTLINE SPOT-ON K' set as best guess, no further details). Dec 2019 as time of administration set as best guess. The owner complained about the missing efficacy. No further information available. Same reporter as DEU-BIAHPV1P-19DE001138, cases are linked.
09-Oct-2019	UAE; 19DK000094; -; Denmark	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.50 Year(s) **Weight:** 4 kg	1	1	1	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	07-Oct-2019	08-Oct-2019	1 Day(s)	D-A	As reported by the animal owner, a cat, 'Mis', domestic breed, male, neutered, 4 kg, 1.5 years, received FRONTLINE POUR-ON VET FOR CATS (LOT R21509AX, EXP SEP 2020, valid) by an unknown route, location and dose, administered by the owner in the evening on 07 OCT 2019. After administration the cat was let outside and did not return to the house before next day. Upon return on 08 OCT 2019 the cat was shaking, had abnormal breathing and did not behave as usual. In the morning on 09 OCT 2019 the cat was found dead in its basket by the owner. UPDATE 15 NOV 2019: Result of post mortem examination: 'No external findings. Thorax was filled with purulent exudate (approx. 250 ml). The purulent fluid was mixed with blood and fibrinclots. The lungs were extensively atelectatic. Pleura and pericardial membranes thickened, unclear and greyishly discoloured with localized fibrin coat. Bacteriological culture: lungs- negative; liver- Pasteurella multocida; thorax- Pasteurella multocida; brain- negative. Remark : Pyothorax (pleura empyema) and chronic pleuritis associated with Pasteurella multocida. Findings of the same batcteria in the liver could indicate sepsis. The pathological findings are chronic and have occurred earlier (more than one week before the cat's death) than the FRONTLINE administration mentioned in the history. The disease mechanism behind the development of pyothorax in cats are not known for certain, but infection arising from bite wounds or penetrating foregin bodies are considered probable contributing causes.'
11-Oct-2019	UAE; 19DK000096; -; Denmark	**Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** - **Age:** 2.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	30-Aug-2019	30-Aug-2019	<=1 hour	D-B	Suspected Adverse Event. As reported by veterinary, a male cat (European shorthaired, 4 kg, 2 years old, neutered and in good state of health) received treatment with Frontline Combo Vet, administered by owner according to label on the 30-08-2019. 1 hour later the cat couldn't walk, was hospitalized with edema in the lungs, was placed in an oxygen cage, recieved fluid therapy, steroids, antibiotics. The cat was at the clinic for 5 days, then sent home with force feeding and treatment. On the 16-09-2019 the cat seemed to feel better and walked around. The cat has previously been treated with this product (on the 07-07-2019) where it reacted with general discomfort/ seemed to be woobling. No other concomitant medication used.

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ED_005739D_00014391-00152

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
09-Oct-2019	UAE; 19DK000098; -; Denmark	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 23 - 25 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Sep-2019*	20-Sep-2019*	0 Day(s)	D-D	As reported by an animal owner, two healthy female intact crossbred dogs (11 years old, 25 kg and 5 years old, 23-24 kg approx.) received FRONTLINE COMBO VET SPOT-ON SOLUTION FOR DOGS 20-40 KG (size L, partial batch number S60619, expiry 02/2021) 1 dose administered topical in the neck by the animal owner for flea treatment (the dogs were itching and the owners had seen one flea on one of the dogs) on 20-SEP-2019. After the treatment, the dogs continued itching and the itching got worse. On the 22-SEP approx., the dogs experienced hair loss on the hind part (caudal part of the back and hind legs), the dogs were biting themselves (itching). The owner bathed the dogs. At the time of the report the itching had decreased but was still ongoing. The dogs had received FRONTLINE COMBO VET in 2018 and experienced the same reaction, but at that time the owners thought it was due to bathing in saltwater.
14-Oct-2019	UAE; 19DK000099; -; Denmark	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 26 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)	12-Oct-2019	14-Oct-2019	2 Day(s)	D-C	As reported by an animal owner, 'Sofus', a 6-months old male Golden retriever (body weight 26 kg) received FRONTLINE COMBO VET (batch number R62510BL, exp. 11/2020 valid) 1 dose once monthly applied topically in the neck by animal owner for prevention on 12-SEP-2019. The day after the owner noticed beginning application site inflammation. In the morning of 14- OCT the skin was red, inflamed, and wet of inflammation at the application site. The owner took the dog to a vet and the dog was treated with one injection Onsior and Isaderm was extradited. The dog had also received FL COMBO VET on the 1-AUG-2019 and in the beginning of SEP-2019 without any reaction.
12-Nov-2019	UAE; 19DK000107; -; Denmark	**Species:** Canine **Breed:** English Bulldog **Sex:** U **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 27.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)	28-Jul-2019	06-Nov-2019*	1 Day(s)	D-B	As reported by att. vet, a 6-months old English bulldog (gender unknown, body weight 27.5 kg) received FRONTLINE COMBO VET for 10-20 kg (lot R62221, exp. SEP-2020, valid partial batch number) 1 dose once monthly topically in the neck administered by the animal owner since 28-JUL-2019 (off-label low dose). The latest dose was given on the 5-NOV, a little less than 24 hours later the owner noticed pruritus and redness in the neck where the product had been applied. The condition worsened and the dog was lethargic at home. On the 8-NOV the dog visited att. vet, clinical examination showed pain from the neck (application site) at touch, an area with erythema and wet fur, pain at touch. The dog was sedated and the area was clipped for closer examination. A larger area in the dorsal neck with diffuse erosion and localized ulceration was observed. The cutis was slightly thickened. Tape test showed neutrophils and some bacteria (not intracellularly). Att. vet assessment: superficial pyo-traumatic dermatitis, possibly due to FRONTLINE. The dog was treated with local microbiological cleanse (Effigel spray 4 times daily after need for at least 5 days), NSAID (Onsior 40 mg 1 tabl q24h for 7 days), and paw socks. On the 11-NOV the dog had developed a larger semi-purulent wound (looking like a deep purulent wound/chemical wound) in the neck region, putrid smell and very tender at touch. Cytology showed moderate number of cocci and few neutrophils. The dog was ordained Tradolan (tramadol) 50 mg 1 tabl 2-3 times daily for 3 days and Clavubactin vet (amox+clav) 260/62.5 mg 1.25 tabl BID for 8 days. On the 12-NOV the wound was cleansed during

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ED_005739D_00014391-00153

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											anaesthesia. Thickened cutis, diffuse areas with excoriations and ulcerations, and satellite lesions with papules was observed. It was cleansed with Efficlean and laser therapy was given. Att. vet assessment: Sands immune mediated drug induced cutaneous reaction. Continued treatment with antibacterial cleanse, NSAID and additional pain
10-Dec-2019	UAE; 19DK000115; -; Denmark	**Species:** Canine **Breed:** English Bulldog **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 22 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Dec-2019	07-Dec-2019	1 Day(s)	D-C	As reported by the animal owner, a dog, 'Bob', male English bulldog, 7 months, 22 kg, received FRONTLINE COMBO VET FOR DOGS size L 20-40 kg (LOT unknown), 1 dose topically applied in the neck area, administered by the animal owner on 06 DEC 2019. The day after product administration, the owner noticed that the application site area looked inflamed. The dog was brought to the vet on 08 DEC 2019 where a bad allergic reaction (not further specified) was found on the neck area. The dog was treated with Medrol vet tablets 4 mg (methylprednisolon), Surolan vet. suspension (Miconazol, polymyxin, prednisolon), Clavubactin vet. tablets (amoxicillin and clavulanic acid), Dexaject (dexamethason inj. solution) and Noromox Prolongatum vet inj. (amoxicillin), dose and frequency unknown for all treatments. On 10 DEC 2019 a new affected neck area was found on the dog by the owner. The dog was brought to the vet again and treated with Betafuse vet gel (betamethason and fusidic acid) and chlorhexidine. A swab was taken from the affected area and sent for culture, results were not available at the time of reporting. The dog has not previously received any flea treatment.
20-Dec-2019	UAE; 19DK000118; -; Denmark	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** - **Age:** 2.00 Year(s) **Weight:** 6.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Oct-2019*	Nov-2019	30 Day(s)	D-D	As reported by the animal owner, a dog, crossbred of Lhasa Apso and Bichon Havanais, female, 2 years old, 6.5 kg, non pregnant, non lactating, received FRONTLINE COMBO VET FOR DOGS 2-10 KG (size S, LOT S60413BL, EXP JAN 2021, valid) 1 pipette applied to the neck area in the autumn 2019 (owner did not remember exact time point, MAH estimated OCT) for treatment against fleas. In NOV 2019 the owner returned the product to the pharmacy, describing that the product did not work. The dog had not been bathed approx one week before and 2 weeks after application. The surroundings had been vacuumed and cleaned. It had previously received treatment against fleas during 2019 (owner did not remember what kind of treatment this was) and had a short break in treatment before receiving FRONTLINE in the autumn. After the owner saw lack of efficacy from FRONTLINE the dog was treated with another topical product as well as tablet treatment with good effect (owner did not remember what this treatment was or if it was prescribed by the att vet).
06-Oct-2019	UAE; 19ES000704; Lleida; Spain	**Species:** Canine **Breed:** Italian Greyhound **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 5.8 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** Seresto collar; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Oct-2019	06-Oct-2019	0 Day(s)	D-C	Suspected Adverse Event: As reported by the animal owner, Nacho, 2 and a half years old (born in MAY17), 5.8 kg, Italian greyhound, male dog received Frontline Spray (batch T00512A and expiry date DEC2021) administrated by the animal owner on 06OCT2019. The owner also put him a Seresto collar. 15 minutes after product administration the animal experienced an intense rash, skin irritation and especially scrotal irritation. The owner bathed the animal and took him to the veterinary clinic where he was treated with corticoids. Vets also prescribed him Diprogenta as a topical treatment. On 07OCT19 the patient was still experiencing scrotal irritation and had to wear a protector collar because he moaned. On 11 OCT19 the owner informed that the animal was almost completely recovered. He only had some little scab. They did not came back to do the check-up. Clinical history: the animal

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ED_005739D_00014391-00154

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											showed red mites and the owner administrated the product on all the areas where the animal had them.
15-Oct-2019	UAE; 19ES000718; Tenerife; Spain	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 3 - 5 kg*	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL SPRAY; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	23-Sep-2019*	05-Oct-2019	12 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal owner, 3 dogs from 3 to 10 years old, from 3 to 5 kg, female mixed breeds (one Yorkshire and two crossbreeds), received 1 pipette of Frontline Combo Spot On dogs 2-10 kg (batch and expiry date unknown) administrated topically by the animal owner approximately on 23SEP2019. Two weeks after product administration the owner realized that each dog had about 2 or 3 fleas. The owner decided to administrate them Frontline Spray (batch and expiry date unknown) administrated topically approximately on 05OCT2019. The fleas seemed to die. However, afterwards the animals had fleas again. Clinical history: these animals live in a country house. They have been receiving Frontline Combo for several years and they never had experienced any flea infestation. They also live with a female cat that usually receives Broadline. This animal has not been infected with fleas.
05-Dec-2019	UAE; 19ES000837; Cantabria; Spain	**Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Unknown **Age:** 1.50 Year(s) **Weight:** 4.8 kg*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jul-2019*	01-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy: As reported by the animal owner, a 1.5 year-old and approximately 4.8 kg, European, male cat received FRONTLINE COMBO SPOT ON CATS (batch R40510BW and expiry date APR2020) by topical route administered by the animal owner seasonally, especially in spring and summer and in autumn depending if it is cold. However, after receiving the last three pipettes the animal continued with fleas. The animal owner also informed that finally another brand name product worked better than Frontline. The animal is an indoor cat.
05-Dec-2019	UAE; 19ES000838; -; Spain	**Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Unknown **Age:** 20.00 Month(s) **Weight:** 5 kg	2	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** FIPRONIL 8.3% / S-METHOPRENE 10% / PRAZIQUANTEL 8.3% / EPRINOMECTIN 0.4% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2019*	01-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy: As reported by the animal owner, a 20 month-old and 5 kg European male cat received FRONTLINE (product assumed to be FRONTLINE SPOT ON CATS as the owner referred to blue pipettes), batch and expiry date unknown, by topical route administered by the animal owner monthly and BROADLINE 2.5-7.5 KG every 3 months (unknown exact administration dates) since he was born. However, in SEP2019 suddenly the owner observed a tick in the neck of the animal that became bigger 2-3 days later. The owner reported a total of 4 ticks in the last 2 months and also observed fleas. Another brand product was finally used and fleas and ticks disappeared. Another animal (about 6 month-old) at home received the same treatment but no fleas or ticks were observed on him. Both animals go out to the street but in this almost 2 years it had never happened before.
01-Oct-2019	UAE; 19FR001179; -; France	**Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON	24-Aug-2019	24-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, two female European cats, aged 2 and 5 years, respectively, 4 kg, in good condition, received each one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: R40309AW, Exp. date: JAN 2020) administered topically by the owner at the base of the neck on 24

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ED_005739D_00014391-00155

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		Age: 2.00 Year(s) **Weight:** 4 kg				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					AUG and 21 SEP 2019 for flea treatment. The product had been administered on a regular basis with a previous administration on 15 JUL 2019. Fleas reappeared after the administration in AUG 2019 (unknown time to onset). No further information was available at the time of this report.
02-Oct-2019	UAE; 19FR001187; -; France	**Species:** Rabbit **Breed:** Dwarf **Sex:** U **Sex qualifier:** Unknown **Age:** 1.75 Year(s) **Weight:** 1.3 kg	1	1	1	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)	21-Sep-2019	24-Sep-2019	3 Day(s)	D-A	FR-ANMV-19 CPVL 01396: D0: Dwarf Lop rabbit applied with 1 pipette of FRONTLINE SPOT ON CHAT. D3: it displayed anorexia. Duration of reaction: < or = 12 hours. Duration of reaction (precision): ongoing (12 hours). Reason for treatment: ectoparasites. Treatment of SAR: not yet. Investigations: none. Outcome of SAR: Unknown. UPDATE from NCA on 18 DEC 2019: Follow-up on 08/10/2019: It died at D14. No precison on exact signs.
07-Oct-2019	UAE; 19FR001212; -; France	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, a cat (unknown signalment and health condition prior to product administration), received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: T40310BW, Exp. date: JAN 2022) administered topically by the owner on an unknown date (01 OCT 2019 was chosen by default) for flea treatment. After product administration (unknown time to onset), fleas were still visible on the animal. No further information was available at the time of this report. Note: the animal lives in the country side and goes outside, in the garden, once per day. It has contacts with a female dog that is treated against fleas (unknown product).
14-Oct-2019	UAE; 19FR001222; -; France	**Species:** Canine **Breed:** Border Collie **Sex:** F **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** BENAZEPRIL; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-May-2019	30-May-2019	0 Day(s)	D-B	Suspected Adverse Event: As reported by the attending vet, a 13-year-old Border Collie dog received FRONTLINE COMBO SPOT ON CHIEN M (BN and exp. date: unknown) administered topically by the owner on 30 MAY 2019. A few hours after product administration, on 30 MAY 2019, the animal experienced agitation, panting, and salivation lasting for 48 hours almost without interruption. Signs then improved but lasted another 48 hours. Complete deafness appeared suddenly. No further information was available at the time of this report. Note: it was reported that FRONTLINE COMBO SPOT ON CHIEN M had been regularly administered (no more details were provided on the frequency of administration) without any reaction. UPDATE ON 25 OCT 2019: The animal was a female and its ID was 2ELE643. It suffered from a cardiopathy (NOS) and was under benazepril. On 03 JUN 2019, the animal had sequelae of deafness but the other signs had disappeared. The vet's level of suspicion was medium.
18-Oct-2019	UAE; 19FR001234;	**Species:** Rabbit **Breed:** Rabbit	1	1	0	**Product used:** FIPRONIL SPOT	05-Oct-2019	09-Oct-2019	4 Day(s)	D-B	FR-ANMV-19 CPVL 01503: D0: rabbit applied with FRONTLINE SPOT ON CHAT. D4: it displayed convulsion. Washed by owner.

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ED_005739D_00014391-00156

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	-; France	(unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 1.2 kg				ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)					D6: presented to vet, convulsions still present. Final outcome not known. Duration of reaction: < or = 48 hours. Duration of reaction (precision): ongoing (48 hours). Reason for treatment: Unspecified. Treatment of SAR: washing. Outcome of SAR: Unknown. Authority comment: FRONTLINE SPOT ON CHAT () : 1 pipette; duration: Once; onset time: < 4 days.
20-Oct-2019	UAE; 19FR001247; -; France	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 3 kg	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	14-Oct-2019	16-Oct-2019	2 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, two 5-year-old spayed female cats, 3 kg, in good condition, received each one pipette of FRONTLINE SPOT-ON CHAT (BN: T20311AX, Exp. date: DEC 2021) administered topically by the owner in the neck on 14 OCT 2019 for flea treatment. 2 days after product administration, on 16 OCT 2019, fleas were visible on the animals. The SLOE was still ongoing at the time of this report.
21-Oct-2019	UAE; 19FR001248; -; France	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** - **Age:** 6.00 Year(s) **Weight:** 7 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	26-Sep-2019	26-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, Benji, a 6-year-old intact male Maltese dog, 7 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHIEN S (BN: F63403AX, Exp. date: OCT 2021) administered topically by the owner between the shoulders on 26 SEP 2019 for flea treatment. The same day, after product administration, fleas were still visible on the animal. No further information was available at the time of this report. Note: the animal had never been treated with a parasiticide before and it had a lot of fleas before administration of FRONTLINE.
23-Oct-2019	UAE; 19FR001251; -; France	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)	19-Oct-2019	20-Oct-2019	1 Day(s)	D-C	FR-ANMV-19 CPVL 01554: D0: cat applied with FRONTLINE SPOT ON CHIEN L. It also licked its haircoat. D1 morning: it displayed muscle tremor. Duration of reaction: < or = 12 hours. Duration of reaction (precision): ongoing. Reason for treatment: fleas. Treatment of SAR: not yet. Investigations: none. Outcome of SAR: Unknown. Authority comment: FRONTLINE SPOT ON CHIEN L () : 1 pipette; duration: once; onset time: 24 hours.
27-Oct-2019	UAE; 19FR001273; -; France	**Species:** Canine **Breed:** Canine various breeds	2	2	0	**Product used:** FIPRONIL SPRAY	26-Oct-2019	28-Oct-2019	2 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, two dogs (one 8-year-old male Yorkshire dog, 3 kg, and one 4-year-old female Labrador dog, 70 kg), in good condition, received

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ED_005739D_00014391-00157

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: X **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 3 - 70 kg				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)					FRONTLINE SPRAY POMPE administered topically by the owner all over the body (about 10 sprays on the Yorkshire and more than 30 sprays on the Labrador) on 26 OCT 2019 in the morning for flea treatment. Two days after product administration, on 28 OCT 2019, fleas were still visible on the animals. No further information was available at the time of this report. Note: a 100 mL vial of FRONTLINE SPRAY POMPE was purchased for the Yorkshire dog (BN: R03706A, Exp. date: SEP 2020) and a 500 mL vial was used for the Labrador dog (BN and exp.date: nos). The Yorkshire lives indoors but the Labrador lives indoors and outdoors. The owner had treated the animals' environment with aerosols from a different brand. She is used to use FRONTLINE SPRAY POMPE and finds that it is not effective anymore.
26-Oct-2019	UAE; 19FR001274; -; France	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	11	11	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019*	01-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, 11 cats (unknown signalment) received each one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN and exp. date: unknown but non expired product according to the owner) administered topically by the owner in the neck on an unknown date (01 OCT 2019 was chosen by default) for flea treatment. After treatment (unknown time to onset), the owner reported a lack of efficacy. She changed of molecule and treated the entire house. No further information was available at the time of this report. Note: the owner had been using FRONTLINE COMBO SPOT ON CHAT for several years without any problems. This case is linked with the case 19FR1275: non-serious SLOE in 9 dogs from the same household after treatment with FRONTLINE TRI-ACT.
04-Nov-2019	UAE; 19FR001290; -; France	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)	03-Nov-2019	04-Nov-2019*	1 Day(s)	D-D	Suspected Adverse Event: As reported by the attending vet, a cat (unknown signalment) received FRONTLINE COMBO SPOT ON CHIEN (product unsubstantiated) (BN and exp. date: unknown) administered topically by the owner on 03 NOV 2019. After product administration (unknown time to onset, date of 04 NOV 2019 mentioned by default as this is the date of reporting), the animal experienced itching on the head and loss of appetite. No further information was available at the time of this report. Off-label use: unauthorised species.
02-Nov-2019	UAE; 19FR001292; -; France	**Species:** Canine **Breed:** Rhodesian Ridgeback **Sex:** X **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 45 - 50 kg	3	3	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	15-Oct-2019	22-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, three 4-year-old Rhodesian Ridgeback dogs (one male weighing 50 kg and 2 females weighing each 45 kg), received each one pipette of FRONTLINE COMBO SPOT-ON CHIEN XL (BN and exp. date: unknown) administered topically by the owner between the shoulders on 15 OCT 2019 for flea treatment. 1 week after product administration, fleas are still visible on the animals. No further information was available at the time of this report. Note: the 3 animals lives partially outdoors.

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* indicates Approximate date or weight.

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ED_005739D_00014391-00158

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
05-Nov-2019	UAE; 19FR001298; -; France	**Species:** Rabbit **Breed:** Dwarf **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 1 kg	2	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)	21-Oct-2019	24-Oct-2019	3 Day(s)	D-B	FR-ANMV-19 CPVL 01588: D0: 2 Dwarf Lop rabbits were applied with FRONTLINE SPRAY POMPE. D3: one of them displayed convulsion. Duration of reaction: < or = 6 hours. Duration of reaction (precision): ongoing (a few hours). Reason for treatment: Curative (ectoparasites). Treatment of SAR: Diazepam to be injected soon. Investigations: none. Outcome of SAR: Unknown. Authority comment: FRONTLINE SPRAY POMPE () : 1 spraying per animal; duration: once; onset time: 3 days.
08-Nov-2019	UAE; 19FR001314; -; France	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 11.00 Week(s) **Weight:** 1.150 kg	1	1	1	**Product used:** FIPRONIL SPRAY **Other products used:** EURICAN CHPPI2L; MILBACTOR; VANGUARD CPV; **Route:** unknown **Was the product used ok?:** Unknown to Company	05-Oct-2019	03-Nov-2019	29 Day(s)	D-A	Suspected Adverse Event: As reported by the attending vet, Pablo born Patapouf, a male Yorkshire puppy born on 16 AUG 2019, ID 250268723013686, 1.150 kg, received EURICAN CHPPi2L (BN: L467482, exp. date: 06 JUN 2020) administered subcutaneously by another vet from another clinic on 07 OCT 2019 as the second injection of primary vaccination. The owners bought the animal in the occasion of a dog exhibition on 26 OCT 2019. During the course of the following week, the animal was not well. On 03 NOV 2019, the animal showed the first signs with slight repeated emesis. On 04 NOV 2019, the animal was dewormed by the owners. On 05 NOV 2019, the animal was brought to the attending vet (no hyperthermia was noticed at this occasion) and received fluid therapy. On 06 NOV 2019, the animal experienced hyperthermia (40°C) and CBC revealed leucopenia. It was put under Interferon but died on 07 NOV 2019. Feces were sampled for potential analysis. The attending vet suspected parvovirosis. No further information was available at the time of this report. Note: the first injection of primary vaccination was done on 21 SEP 2019 with VANGUARD CPV (BN: L346998, exp.date: 07 JUN 2022). The puppy also received MILBACTOR on 03 OCT 2019 and Frontline Spray on 05 OCT 2019. UPDATE ON 18 NOV 2019: On 14 NOV 2019, PCR analysis was performed on feces: positive for parvovirus with a viral load of 2.42x10exp7 compatible with parvovirosis. The case was changed into a suspicion of lack of efficacy.
13-Nov-2019	UAE; 19FR001324; -; France	**Species:** Feline **Breed:** Abyssinian **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Oct-2019	19-Oct-2019	0 Day(s)	D-C	Suspected Adverse Event: As reported by the animal's owner, a 3-year-old female Abyssinian cat, 3 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: T40310BW, Exp. date: JAN 2022) administered topically by the owner on 19 OCT 2019 for flea treatment. The product was correctly administered at the base of the neck between the shoulders but it did not prevent the animal to lick itself. On the same day (unknown time to onset), after product administration, the animal experienced severe drooling, was not well, apathic. It did not move anymore and began to tremble. It displayed inflammation of the lips and whiskerpads. The animal usually moves a lot but at this time it stayed in its box. The owner brought the animal to the vet who injected a product (NOS) for the treatment of lip and whiskerpad swelling. The animal stayed under monitoring at the clinic for 3 hours and then recovered.
14-Nov-2019	UAE; 19FR001327;	**Species:** Feline **Breed:** European	1	1	0	**Product used:** FIPRONIL SPOT	05-Nov-2019	07-Nov-2019*	2 Day(s)	D-C	FR-ANMV-19 CPVL 01686: D0: European cat applied with FRONTLINE SPOT ON CHIEN L. D2: it displayed muscle tremor.

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ED_005739D_00014391-00159

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; France	**Sex:** M **Sex qualifier:** - **Age:** - **Weight:** 4 kg				ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)					Note : signs may have begun before D2, but not sure. Duration of reaction: < or = 6 hours. Duration of reaction (precision): ongoing. Reason for treatment: fleas. Treatment of SAR: washing. Investigations: none. Outcome of SAR: Unknown. FRONTLINE SPOT ON CHIEN L () : 1 pipette; duration: once; onset time: < 48 hours.
15-Nov-2019	UAE; 19FR001331; -; France	**Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Neutered **Age:** 5.30 Year(s) **Weight:** 3.7 kg	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jan-2018	01-Jan-2018	0 Day(s)	D-A	FR-ANMV-19 CPVL 01673: Case reported by owner 22 months after incident had occured. European cat in good general condition (despite Felv positive test). January 1st: applied with FRONTLINE COMBO SPOT-ON CHAT. Within 6 hours, it displayed severe vomiting and anorexia. January 3rd: vet prescribed antibiotic (clindamycin), but the cat sometimes vomited capsule. January 11: cat injected with NSAID, and prescribed with doxycycline. The cat had lost weight, and vomited tablet. January 12: diagnosis of "irreversible anaemia" (CBC not provided). Prescribed with vitamins, antacid. January 23: blood work-up yielded "irreversible anaemia" and "muscular injury" (coded as muscle inflammation). Results not provided. Decision of euthanasia. Note: previous application (November 2017) had been associated with transient apathy and reddening at application site (these signs were not coded, as not in the same incident). Duration of reaction: < or = 30 days. Duration of reaction (precision): 23 days. Reason for treatment: preventive. Treatment of SAR: ANTIROBE (clindamycin) 75 mg/d, TOLFEDINE (tolfenamic acid) injection, DOXYVAL (doxycycline) 50 mg/d, TONIVIT (vitamins), ZITAC (cimetidine) 50 mg bid. Outcome of SAR: Unfavorable. Authority comment: FRONTLINE COMBO SPOT-ON CHAT () : 1 pipette; duration: Once; onset time: < 6 hours.
15-Nov-2019	UAE; 19FR001332; -; France	**Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Neutered **Age:** 3.25 Year(s) **Weight:** 4-5 kg	1	1	1	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	15-Sep-2019	15-Sep-2019	0 Day(s)	D-A	FR-ANMV-19 CPVL 01675: D0 (2 pm): European cat administered with FRONTLINE SPOT ON CHAT. Same day, it displayed decreased activity, decreased appetite. Over the next weeks, the cat appeared fine. D34: over 12 hours, sudden onset of mewing, hiding. D35, 2 pm: presented to emergency vet. A presentation, lethargy, hypothermia (36.5°C), pallor, dehydration (5%). Normal abdominal palpation. CBC showed anaemia (RBC 1.99 T/L, PCV 9.1%, haemoglobin 2.9 g/dL) ; low reticulocytes count (0.9 G/L), low platelet count (39 G/L). Presumptive diagnosis of immune-mediated haemolytic anaemia. Despite intensive care (oxygen, fluids, antibiotics, glucocorticoid), condition worsened in the afternoon, and the cat died after cardiorespiratory arrest. Note: first application of the product (previously administered with spinosad). Note 2: owner had concern regarding adverse event, and intended to share with animal protection association. Duration of reaction: > 30 days. Duration of reaction (precision): 5 weeks. Reason for treatment: preventive. Treatment of SAR: fluid therapy: saline, oxygen, DOXYVAL (doxycycline), DERMIPRED (prednisolone). Investigations: normal coagulation test, normal blood chemistry (ALT, ALKP, bilirubin, creatinine), Felv-FIV: negative test. Outcome of SAR: Unfavorable. Authority comment: FRONTLINE SPOT ON CHAT () : 1 pipette (neck); duration: Once; onset time: < 12 hours.

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ED_005739D_00014391-00160

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
19-Nov-2019	UAE; 19FR001345; -; France	**Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 4 kg*	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	31-Oct-2019	31-Oct-2019	Immediately	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, three European cats aged 3, 15, and 17 years, respectively, and weighing approximately 4 kg, in good condition, received each one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN and exp. date: unknown) administered topically by the owner between the shoulders on 31 OCT 2019 for flea treatment (fleas visible on animals prior to treatment). The owner reported a complete lack of efficacy after product administration (nos). No further information was available at the time of this report.
21-Nov-2019	UAE; 19FR001350; -; France	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** - **Weight:** Unknown	9	6	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** BRAVECTO 250 MG SOLUTION POUR SPOT-ON POUR CHATS DE TAILLE MOYENNE (> 2,8 - 6,25 KG); **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jun-2018*	01-Jun-2018*	0 Day(s)	D-C	FR-ANMV-19 CPVL 01672: Case notified with poor info and mixed species. Case also notified and associated with 19CPVL01690, same signs in dogs (of same owner). 2018: 9 cats were administered with both FRONTLINE SPOT ON CHAT and BRAVECTO 250 MG SOLUTION POUR SPOT-ON POUR CHATS DE TAILLE MOYENNE (> 2,8 - 6,25 KG). Note : not especially in the same time, unknown possibility of association. Quickly, they displayed hypersalivation, hyperthermia, associated with application site lesions : pruritus, erythema, followed by alopecia. Recovery with care within weeks. Duration of reaction: > 30 days. Duration of reaction (precision): weeks. Reason for treatment: ectoparasites. Treatment of SAR: Unprecised local care. Investigations: ? Outcome of SAR: Favorable. Authority comment: FRONTLINE SPOT ON CHAT () : ?; duration: once; onset time: immediately, BRAVECTO 250 MG SOLUTION POUR SPOT-ON POUR CHATS DE TAILLE MOYENNE (> 2,8 - 6,25 KG) () : ?; duration: once; onset time: immediately
21-Nov-2019	UAE; 19FR001351; -; France	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** - **Weight:** Unknown	9	6	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** BRAVECTO 500 MG SOLUTION POUR SPOT-ON POUR CHIENS DE TAILLE MOYENNE (> 10 - 20 KG); **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jun-2018*	01-Jun-2018*	0 Day(s)	D-C	FR-ANMV-19 CPVL 01690: Case notified with poor info and mixed species. Case also notified and associated with 19CPVL01672, same signs in cats (of same owner). 2018: 9 dogs were administered with both (supposed) FRONTLINE SPOT ON CHIEN and BRAVECTO 250 MG SOLUTION POUR SPOT-ON POUR CHIENS DE TAILLE MOYENNE (> 10-20 KG). Note : not especially in the same time, unknown possibility of association. Quickly, they displayed hypersalivation, hyperthermia, associated with following application site lesions : pruritus, erythema and alopecia. Recovery with care within weeks. Duration of reaction: > 30 days Duration of reaction (precision): weeks. Reason for treatment: ectoparasites. Treatment of SAR: unkown local care. Investigations: ? (unknown if vet examination). Outcome of SAR: Favorable.
21-Nov-2019	UAE;	**Species:** Feline	1	1	0	**Product used:**	08-Nov-2019	09-Nov-2019	1 Day(s)	D-B	FR-ANMV-19 CPVL 01701: D0: European cat applied with

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ED_005739D_00014391-00161

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19FR001354; -; France	**Breed:** European **Sex:** M **Sex qualifier:** - **Age:** - **Weight:** 7 kg				FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)					FRONTLINE SPOT ON CHIEN. Note: lives with a dog, but no contact (conflictual contexte), no possible mutual licking. D1: it displayed muscle tremor. D2 : same tremors. D3 noon : vet consultation. Vet washed the cat; at the end of washing, cat began crisis of convulsion. Duration of reaction: < or = 7 days. Duration of reaction (precision): ongoing (< 3 days). Reason for treatment: fleas. Treatment of SAR: washing, medetomidine, diazepam 10 mg. Investigations: permethrine exposure ? Outcome of SAR: Unknown. Authority comment: FRONTLINE SPOT ON CHIEN () : 1 pipette; duration: once; onset time: < 24 hours.
27-Nov-2019	UAE; 19FR001364; -; France	**Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 5 kg	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	11-Oct-2019	25-Oct-2019	2 Week(s)	D-D	FR-ANMV-19 ANMV 02234. For curative treatment (treatment of fleas) two European cats were applied one pipette FRONTLINE SPOT ON CHAT by the veterinarian (who is the owner of the cats) on 11/10/2019. On 25/10/2019, the veterinarian reported a total inefficacy of the product against fleas (no more precision). Note: the veterinarian reported also lethargy after application on the cats (see linked report FR-ANMV-19 ANMV 02368).
27-Nov-2019	UAE; 19FR001365; -; France	**Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** - **Age:** 2.00 Year(s) **Weight:** 5 kg	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	11-Oct-2019	11-Oct-2019	0 Day(s)	D-D	FR-ANMV-19 ANMV 02368: For curative treatment (treatment of fleas) two European cats were applied one pipette FRONTLINE SPOT ON CHAT by the veterinarian (who is the owner of the cats) on 11/10/2019. Thirty minutes later, the cats displayed acute lethargy that lasted about 13 hours. No treatment, only medical monitoring. Total recovery. Note: the veterinarian reported also lack of expected efficacy after application of the pipette on the cats (see linked report FR-ANMV-19 ANMV 02234). Duration of reaction:13 Hours. Reason for treatment: Curative.
27-Nov-2019	UAE; 19FR001384; -; France	**Species:** Canine **Breed:** Cavalier King Charles **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 10 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	23-Nov-2019	24-Nov-2019	N/A	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, a 8-year-old female Cavalier King Charles dog, 10 kg, in good condition, received more than 20 sprays of FRONTLINE SPRAY POMPE (BN: S03004A, Exp. date: NOV 2021) administered topically by the owner between 23 and 27 NOV 2019 for flea treatment. Less than 1 day after product administration, on 24 NOV 2019 in the morning, fleas were still visible on the animal. No further information was available at the time of this report. Note: the animal lives partially outdoors and with a kitten that lives exclusively indoors that also experienced a lack of efficacy (fleas) after treatment with the same product at the same time: case number: 19FR1385. The owner regularly cleans the house.
27-Nov-2019	UAE; 19FR001385; -; France	**Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products	23-Nov-2019	24-Nov-2019	N/A	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, a 4-month-old male European kitten, 2 kg, in good condition, received more than 10 sprays of FRONTLINE SPRAY POMPE (BN: T00312A, Exp. date: DEC 2021) administered topically by the owner between 23 and 27 NOV 2019 for flea treatment. Less than 1 day after product administration, on 24 NOV 2019 in the

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ED_005739D_00014391-00162

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Month(s) **Weight:** 2 kg				**Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					morning, fleas were still visible on the animal. No further information was available at the time of this report. Note: the animal lives exclusively indoors but with a dog that lives partially outdoors that also experienced a lack of efficacy (fleas) after treatment with the same product at the same time: case number: 19FR1384. The owner regularly cleans the house.
28-Nov-2019	UAE; 19FR001386; -; France	**Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 4.2 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	04-Nov-2019	04-Nov-2019*	N/A	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, Fibonacci, a 6-year-old spayed female crossbred Angora and European cat, 4.2 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: S41513CW, Exp. date: NOV 2021) administered topically by the owner between the shoulders on 04, 07, and 15 NOV 2019 for flea treatment. After product administration (unknown time to onset), fleas were still visible on the animal. The attending vet saw hair balls with flea eggs. However, the owner reported a good efficacy on the cat's environnment (no infestation). On 18 NOV 2019, the animal was treated with FRONTLINE SPRAY and no more fleas were seen on the animal. Note: the animal had previously received (unknown date) Midaspot for more than 4 kg. The owner had treated the environment with 7 Foggers in prevention.
04-Dec-2019	UAE; 19FR001392; -; France	**Species:** Other **Breed:** Hedgehog **Sex:** M **Sex qualifier:** - **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)	20-Nov-2019	21-Nov-2019	1 Day(s)	D-B	FR-ANMV-19 CPVL 01772: D0 noon: recently found Hedgehog presented to animal shelter with 15 ticks. Good general condition. Applied with FRONTLINE SPRAY POMPE 1,5 ML (500 mL bottle) (a few pump activation on a gauze, applied gently on skin). Afternoon, good behaviour, good appetite. D1 morning: moderately dynamic. At noon, it displayed coma, associated with bradypnoea. Duration of reaction: < or = 6 hours. Duration of reaction (precision): ongoing (3 hours). Reason for treatment: ticks. Treatment of SAR: none. Outcome of SAR: Unknown. Authority comment: FRONTLINE SPRAY POMPE 1,5 ML () : a few pump activation on a gauze; duration: once; onset time: < 24 hours.
10-Dec-2019	UAE; 19FR001404; -; France	**Species:** Canine **Breed:** Bernese Mountain Dog **Sex:** M **Sex qualifier:** - **Age:** 3.80 Year(s) **Weight:** 45 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Nov-2019	17-Nov-2019	1 Day(s)	D-C	FR-ANMV-19 CPVL 01767: D0: Bernese Mountain Dog applied with FRONTLINE COMBO SPOT-ON CHIEN XL (first application). D1: onset of signs. D4: presented with purulent lesion (pyoderma/hot spot) around application site (20 cm diameter). Final outcome not known. Duration of reaction: < or = 7 days. Duration of reaction (precision): ongoing (< 4 days). Reason for treatment: preventive. Treatment of SAR: hair clipping (under anaesthesia) dexamethasone, co-amoxiclav, disinfection, Topical CORTANMYCETINE (chloramphenicol-prednisolone). Outcome of SAR: Unknown. Authority comment: FRONTLINE COMBO SPOT-ON CHIEN XL () : 1 pipette; duration: Once; onset time: < 24 hours.
16-Dec-2019	UAE; 19FR001433; -; France	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other	01-Dec-2019	01-Dec-2019	0 Day(s)	D-B	FR-ANMV-19 CPVL 01818: Case with poor information. Cat applied with one half pipette of FRONTLINE SPOT ON for 20-40kg dog. Same day, it displayed coma with stiffness, myoclonus (jaw and lumbar area) and paddling. Duration of reaction: < or = 1 hour. Duration of reaction (precision): ongoing. Reason for treatment:

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ED_005739D_00014391-00163

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** - **Weight:** 5 kg				products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)					preventive. Treatment of SAR: Diazepam. Outcome of SAR: Unknown. Authority comments: FRONTLINE SPOT ON CHIEN L () : one half pipette; duration: once; onset time: < 24 hours.
10-Dec-2019	UAE; 19FR001434; -; France	**Species:** Feline **Breed:** European **Sex:** X **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 4 - 5 kg	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	12-Oct-2019	12-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, two neutered European cats (a 10-year-old female and a 2-year-old male), 4-5 kg, in good condition, received one pipette of FRONTLINE SPOT-ON CHAT (BN and exp. date: unknown) administered topically by the owner between the shoulders on 12 OCT, 27 OCT and 11 NOV 2019 for flea treatment (fleas present on the animals). The owner did not observe any improvement after treatment (unknown time to onset). The animals received then FRONTLINE COMBO SPOT ON CHAT (BN: T40116DW; exp. date: DEC 2021) administered topically between the shoulders by the owner on 06 DEC 2019 but with no better results. No further information was available at the time of this report.
18-Dec-2019	UAE; 19FR001464; -; France	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Not applicable **Age:** 12.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Dec-2019	06-Dec-2019	1 Day(s)	D-D	FR-ANMV-19 CPVL 01857: D0: cat administered with FRONTLINE SPOT ON CHAT (allegedly, first application). D1: presented with decreased appetite, lethargy. Final outcome not known. Duration of reaction: < or = 6 hours. Duration of reaction (precision): ongoing (< 6 hours). Reason for treatment: preventive. Investigations: none at time of phone call report. Outcome of SAR: Unknown. Authority comment: FRONTLINE SPOT ON CHAT () : 1 pipette; duration: Once; onset time: < 24 hours.
08-Dec-2019	UAE; 19FR001499; -; France	**Species:** Canine **Breed:** Shepherd Dog (Others) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 30 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)	01-Dec-2019*	01-Dec-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, a 1-year-old neutered male Shepherd dog, 30 kg, in good condition, received 30 sprays of FRONTLINE SPRAY POMPE 500 mL (BN: T00201A, Exp. date: DEC 2021) administered topically by the owner all over the body at the beginning of DEC 2019 for flea treatment (fleas seen on the animal). After product administration (unknown time to onset), the animal experienced a lack of efficacy. FRONTLINE SPRAY 500 mL (BN: T00201A, Exp. date: DEC 2021) (30 sprays) was readministered on 15 DEC 2019 without any efficacy. No further information was available at the time of this report. Off-label use: underdosed (the animal (30 kg) should have received 60 sprays instead of 30).
26-Dec-2019	UAE; 19FR001501; -; France	**Species:** Canine **Breed:** Canine Other **Sex:** M **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 20 kg	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** FIPRONIL SPOT ON DOG; **Route:** Topical /	11-Dec-2019	11-Dec-2019*	N/A	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, two 11-year-old male Lagoto Romagnolo dogs, 20 kg, in good condition, received each one pipette of FRONTLINE SPOT-ON CHIEN L (T00708A, Exp. date: JAN 2022) administered topically by the owner between the shoulders on 11, 12, and 19 DEC 2019 and FRONTLINE SPRAY administered topically all over the body by the owner every other day from 11 to 19 DEC 2019 for flea treatment (fleas visible on the animals). After product

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ED_005739D_00014391-00164

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** Unknown to Company					administration (unknown time to onset), fleas were still visible on the animals. No further information was available at the time of this report.
01-Oct-2019	UAE; 19IT000115; -; Italy	**Species:** Canine **Breed:** Missing Dog (do not use) **Sex:** U **Sex qualifier:** Unknown **Age:** UNKNOWN **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Jul-2019*	Jul-2019	N/A	D-D	As reported by the owner, a dog, received Frontline Combo Spot on 2-10 kg administered by the owner between July-August 2019. The owner suspects lack of efficacy because her dog already experience fleas on its skin.
21-Oct-2019	UAE; 19IT000119; -; Italy	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 4.6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON; **Route:** unknown **Was the product used ok?:** No (zzOff label use / Indication)	17-Oct-2019	17-Oct-2019	N/A	D-D	As reported by the owner, 2 cats, 4.6 kg weight and 8.6 kg weight, received 2 doses of Frontline Combo Spot on Cats administered by the owner. To the first cat (4.6 kg) the product was administered on 08 Oct 2019 and on 17 Oct 2019. To the second cat (8.6 kg) the product was administered on 07 Oct 2019 and on 20 Oct 2019. In both cases after product administration animals experienced alrealdy fleas on their skin.
07-Nov-2019	UAE; 19IT000128; -; Italy	**Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Nov-2019	04-Nov-2019	N/A	D-B	As reported by owner, 2 cats, 5 months old (male) and 15 years old (female), received Frontline (unknown if it was Combo or Spot on) administered by the owner on 04 Nov 2019. The youngest cat, 90 minutes after product administration the animal experienced apathy, trembling, kicking with paws, difficulty walking. It has been brought to the clinic and the Vet administered cortisone. Symptoms then got worse: the cat experienced midryasis, rigidity, trembling, lack of appetite and tachypnea) and the next day (05/11/2019) the cat was brought again to the hospital where liquids were administered (unknown if it recovered). The oldest cat experienced same symptomatology with strongly trembling, drooling and anuria. It has been brought to the clinic and received the same treatment with more liquids than the other cat and recovered.
08-Nov-2019	UAE; 19IT000129; -; Italy	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F	1	1	0	**Product used:** FIPRONIL SPRAY **Other products**	Nov-2019*	Nov-2019*	N/A	D-D	As reported by Pharmacist, 2 dogs, Poodle, male (2 months old, 500 grams weight) and female (4 years old, 5 kg weight), received 1 dose of Frontline Spray, batch number A103029029, exp date 11/2021, administered by the owner.

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ED_005739D_00014391-00165

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: - **Age:** 4.00 Year(s) **Weight:** 5 kg				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (zzOff label use / Indication)					After product administration they experienced already fleas on them skin. The owner suspect lack of efficacy. The owner has sprayed the product one time on the male and two times on the female. As reported by the Vet, the administration of the product has not been correct because the dosage was low.
19-Nov-2019	UAE; 19IT000133; -; Italy	**Species:** Feline **Breed:** Ragdoll **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Others)	17-Nov-2019	17-Nov-2019	N/A	D-D	As reported by the owner, a cat, male, Ragdoll, 2 years old, 8 kg weight, received Frontline Combo Spot on Cats administered by the owner on 17 Nov 2019. 2 days after product administration the animal experienced already fleas on its body but the owner declared that the product has been adminitered not according the correct administration way (product put on the hair and not on the skin). The cat lives in home.
06-Dec-2019	UAE; 19IT000142; -; Italy	**Species:** Feline **Breed:** European **Sex:** X **Sex qualifier:** - **Age:** - **Weight:** Unknown	10	10	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL SPOT ON CAT; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	2019*	2019*	N/A	D-D	10 cats more or less, mostly European, mixed female and male, received Frontline Spot On Cats and Frontline Combo Spot On Cats during the antiparassitary season (during 6/7 months in 2019). All these cats experienced during this period alopoecia, irritation on the product application site. They were not treated after the adverse reactions but recovered.
11-Dec-2019	UAE; 19IT000146; -; Italy	**Species:** Canine **Breed:** Pomeranian **Sex:** U **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	10-Dec-2019*	10-Dec-2019*	N/A	D-D	As reported by the owner, a dog, Pomeranian, 3 years, 4 kg weight approximately, received Frontline Combo Spon On Dogs 2-10 kg, batch number F62816AL, exp date 09/2021, administered by the owner on 10/12/2019. The owner suspect lack of efficacy ; unknown if against fleas or ticks and no additional information are available eben after additional contact with the owner. The owner reported that everything was solved. During the following day (11/12/2019) the owner administered again the medicinal product: this is a overdose as 2 administration of the product in 2 days are not in line with product indication.
16-Dec-2019	UAE; 19IT000148; -; Italy	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** U **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	05-Dec-2019	05-Dec-2019	N/A	D-D	As reported by the owner, a dog, Poodle, 3 years old, 5 kg weight approximately, received Frontline Combo Spot On 2-10kg, administered by the owner on 05/12/2019. After product administration the animal still experienced fleas on its skin and the owner suspected lack of efficacy.

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ED_005739D_00014391-00166

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 3.00 Year(s) **Weight:** 5 kg				**used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					
18-Dec-2019	UAE; 19IT000149; -; Italy	**Species:** Canine **Breed:** Hound Breeds (200 Series) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 17 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Dec-2019*	Dec-2019*	N/A	D-D	As reported by the owner, a dog, Hound, 17 kg weight, received Frontline Spray (unknown if 100 ml or 250 ml bottle) administered by the owner and after product administration it experienced vomit and for this reason it has been brought to the clinic because of intoxication. The owner administrated Frontline Spray to her other dog and it didn't experienced an adverse reaction. No more info received.
23-Dec-2019	UAE; 19IT000150; -; Italy	**Species:** Feline **Breed:** Persian (No Further Description) **Sex:** F **Sex qualifier:** - **Age:** 9.00 Year(s) **Weight:** 5 - 6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	20-Oct-2019*	Oct-2019*	N/A	D-D	As reported by the owner, a cat, female, 5.8 Kg weight, 9 years, persian, received Frontline Combo Spot On Cats, batch T40301AW exp. 1-2022, during the antiparassitary season. Last administration done on October 2019, and previously each month The cat has access to the external part of the house. She started to show presence of fleas with continous itching during the day and the night The owner reported that The cat is large enough in size to be a female and although the hair is not very long like her mother (pure Persian), however, it is still long enough very fine and very dense, in this period it is almost impossible to see the skin). The owner decided to use Avantage and the problem was solved
01-Oct-2019	UAE; 19JP000211; Gunma; Japan	**Species:** Feline **Breed:** Feline various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Week(s) **Weight:** 250 gms	1	1	1	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	30-Sep-2019	30-Sep-2019	0 Day(s)	D-A	As reported by the attending veterinarian, about 4-week-old, 250 g, male, mixed breed cat recently weaned was found infested with flea about 1 week ago of 30 Sep 2019. Although the animal was not brought to the hospital, Frontline spray (Lot number: R02804A, Expiry date: Jun-2019, Topcal, 1.8 ml/head) was put in an eye drop bottle and prescribed on the day. At around 7:00 pm on the same day, the owner administered all the solution on the back of the neck. 1.8 ml was overdose. About 1 hour after administration, the cat developed slow movement (paralysis or collapse?), slow breathing and died at around 7:40 am the next day. No examination was performed.
07-Oct-2019	UAE; 19JP000214; Shimane; Japan	**Species:** Feline **Breed:** Feline various breeds **Sex:** M **Sex qualifier:** - **Age:** 1.00 Month(s) **Weight:** 300 gms	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	06-Oct-2019	06-Oct-2019	0 Day(s)	D-C	As reported by the attending veterinarian, at 9 AM on 06 Oct 2019, a 1-month-old, 300 g, male, intact, mix cat, which the owner got from an acquaintance at the age of 3 days, was brought to the hospital. Although the cat had loose stool twice on 05 Oct 2019, there was no apparent physical problem at the time of the visit. Accordingly, Frontline Spray (Lot number: S00202A, Expiry date: Dec-2019, topical, 3 mL / kg) was administered to the cat by the attending veterinarian. At about 2 PM on 06 Oct 2019, the cat developed anorexia. At about 5 PM, loss of vigor, vomiting,

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ED_005739D_00014391-00167

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					increased heart rate, and fever were observed. At about 10:30 PM, the condition improved a little, but from about 12 AM to the morning on 07 Oct 2019, vomiting and diarrhea continued. At 9 AM on 07 Oct 2019, the cat was brought to the hospital, and the veterinarian examined it. Since the above symptoms were relieved, a wait-and-see approach was taken. On 07 Oct 2019, the owner called the attending veterinarian and reported that the vomitting and diarrhea had not been observed. The attending veterinarian regarded that the cat recovered on 08 Oct 2019.
21-Nov-2019	UAE; 19JP000258; Chiba; Japan	**Species:** Canine **Breed:** Poodle (Toy) **Sex:** U **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	02-Nov-2019	02-Nov-2019	0 Day(s)	D-D	As reported by the animal owner, on 02 Nov 2019, Frontline Plus (Lot number: S61020BL, Expiry date: Apr-2021, Topical, 1 pipette, 0.5 mL/head) was administered to 3 toy poodles (9 years old, 7 years old and 1.5 years old, body weight unknown, gender unknown). The 9-year-old dog developed diarrhea the next day. The 7-year-old dog vomited on the day of administration and the next day. The 1.5-year-old dog vomited twice on the day of administration and also vomited the next day and the day after. Since the drug was purchased via online, the attending veterinarian's opinion is unknown.
23-Dec-2019	UAE; 19JP000273; Ehime; Japan	**Species:** Feline **Breed:** Feline various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 5.5 kg*	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	20-Dec-2019	20-Dec-2019	0 Day(s)	D-A	As reported by the animal owner, on 20 Dec 2019, Frontline Plus Cat (Lot number and Expiry date: Unknown, Topical, Dose: Unknown) was administered to a 12 year old, 5-6 kg, female Japanese cat by the animal owner (elderly woman). The owner could not successfully apply it between the cat's shoulder blades and the cat seems to have licked the drug solution. Several hours after administration, the cat began to vomit and lost her energy and appetite. Although the owner called the clinic where the drug had been prescribed, she could not take the cat there immediately. There was also no veterinary clinic nearby for a night emergency, and the owner was going to take her to the clinic on 23 Dec 2019. However, the cat was dead this morning. As the cat could not eat or drink anything on her own for about 2 days, she was force fed with a syringe yesterday.
14-Oct-2019	UAE; 19KR000032; -; South Korea	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Iverhart (Company: Virbak); **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	02-Oct-2019	04-Oct-2019	2 Day(s)	D-D	Suspected Adverse Event: As reported by the attending vet on 14 Oct 2019, a dog (Maltese, 10Y8M, 5kg, neutered male) was adminstered FRONTLINE PLUS DOG S (batch no: S63007AL, exp date: September 2021, application site: Back neck, storage conditions: room temperature, no known defects, 1 dose) by the vet on 2nd October 2019. The dog has been adminstered with the product before and had shown AE (4-5 years prior, no other details). Administration was for ticks, and had been adminstered with Virbak's Iverhart by the vet on the same day (1 dose, administration reason: heartworm prevention, application site: PO, 1 dose, no defects). Symptoms included hair loss, skin flare and irritation, flaky skin which occured on 4th October 2019. The dog was given antiseptic ointments and antiinflammatory, antibiotic medication for future prevention. The dog is recovering and is 90% recovered at the time of report.
21-Oct-2019	UAE; 19KR000033;	**Species:** Canine **Breed:** Poodle	1	1	0	**Product used:** FIPRONIL	18-Oct-2019	21-Oct-2019	0 Day(s)	D-C	Suspected Adverse Event: As reported by attending vet, a dog (Poodle, 8Y, 8kg, neutured male) was administered with Frontline

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ED_005739D_00014391-00168

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; South Korea	(Miniature) **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 8 kg				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					Plus Dog S (batch no: S62201AL, exp date: September 2020) application site: Back neck, storage conditions: room temperature, no known defects, 1 dose by the dog owner on 18th October 2019. The dog had been adminstered with the product before with no prior AE. The treatment was for prevention of ticks and the dog was in a healthy state. The dog started showing symptoms on 21st October 2019 which include suspicion of hair loss, skin flare and irritation, and pain. The vet prescribed antihistamines for treatment, which is ongoing.
13-Nov-2019	UAE; 19KR000036; -; South Korea	**Species:** Canine **Breed:** Eskimo (Spitz) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.50 Year(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Corona vaccine; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	21-Oct-2019*	10-Nov-2019	20 Day(s)	D-C	Suspected Lack of Efficacy and Adverse Event: As reported on 13 Nov 2019 by the attending vet, a dog (Spitz, 4Y7M, 6kg, neutered male) was administered with Frontline Plus S (batch no: S61908BL, exp date: July 2021, application site: Back neck, storage conditions: room temp., 1 dose) by the vet on 21 Oct 2019 for prevention of ticks. The dog had been administered with the product before and had shown an AE previously (no details were reported). The dog was otherwise in good health. The dog was also given Corona vaccine on the same day (via SC, 1cc dose, storage at room temperature) for prevention of the virus. The adverse effects started on 10 Nov 2019 when the dog was bitten by a tick underneath its chin. The owner removed it but its mouth was stuck on the skin. The AE included inflammation, redness and edema. The dog was given antibiotic ointments and is still being treated.
01-Oct-2019	UAE; 19NL000190; -; Netherlands	**Species:** Canine **Breed:** - **Sex:** F **Sex qualifier:** - **Age:** 12.00 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** - **Was the product used ok?:** Unknown to Company	Sep-2019*	Sep-2019*	N/A	D-D	SLOE, client previously used Fronline Spot-On had started with Frontline combo since this month. It is not clear why clients switched products as she had no previous problems, however she states this product should treat the whole house. Dog is itching and a single flea is found on the dog. Owner states that she has crushed many flee eggs between the finger nails which were found on the dog, states these eggs are brown. Explanation that this might be flea poop found on the dog and explanation on how to differentiate leads to lots of emotions from owner. Not clear if animal comes into contact with other animals or if there are cats in the household.
04-Oct-2019	UAE; 19NL000193; -; Netherlands	**Species:** Feline **Breed:** - **Sex:** U **Sex qualifier:** - **Age:** 1.00 Year(s) **Weight:** 2 - 6 kg*	5	5	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** - **Was the product used ok?:** Unknown to Company	Sep-2019	Sep-2019*	N/A	D-D	Household 5 cats, SLOE. Owner has never used any product against fleas, only when flees are present. Thus started with product with many fleas present in the house. Used the product 3 weeks ago, still fleas present. Used also Beaphar anti conception product, still fleas present. Owner states that cleaning lady also introduces new fleas into the household. Product and how to use it is explained how it works and when results can be seen in flea infested place.
02-Oct-2019	UAE; 19NL000199; -; Netherlands	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	N/A	28-Sep-2019	29 Day(s)	D-D	As reported by pet owner, a 3 year old female German Sheppard dog weighing 30 kilo of unknown reproductive status received FRONTLINE COMBO DOG L expiry date and batch number unknown cutaneous between the shoulder blades from the dog owner for an extended period every 4 weeks, latest administration

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* indicates Approximate date or weight.

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ED_005739D_00014391-00169

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** 3.00 Year(s) **Weight:** 30 kg				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					date 30-aug-2019. 1 month after latest product administration, on 28-sep-2019, owner found a flea on the dog and dog bites bold spots, presumably itching due to flea. It is unknown if the dog goes outside or has contact with other animals. Unknown if the dog is housed with other animals. Veterinarian prescribed Advantage, which was administered on 02-oct-2019. Outcome of the reaction is not reported.
04-Oct-2019	UAE; 19NL000200; -; Netherlands	**Species:** Feline **Breed:** European **Sex:** U **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 4 kg	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	25-Sep-2019*	10 Day(s)	D-D	As reported by pet owner, 2 European cats, 5 years old, weighing 4 kilos, unknown sex and of unknown reproductive status received FRONTLINE SPOT ON CAT expiry date feb-2021 and batch number unknown, by the cat's owner cutaneous between the shoulder blades for years with 4 weeks in between. Latest product application was approximately on 15-sep-2019. After last product administration, the owner reports she found a couple of fleas on the cats on 25-sep-2019. Cats go outside. It is unknown if the cats have contact with other animals. The cats are not housed with other animals. Outcome of the reaction is not reported.
21-Oct-2019	UAE; 19NL000212; -; Netherlands	**Species:** Feline **Breed:** - **Sex:** U **Sex qualifier:** - **Age:** 9.00 Week(s) **Weight:** Unknown	5	5	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	25-Sep-2019	21-Oct-2019*	2 Day(s)	D-D	As reported by animal owner, 5 3-week-old cats, unknown sex, breed and weight received FRONTLINE SPRAY, unknown use and dose, from the cat's owner at least three and some even 4 times between 25-sep-2019and 19-oct-2019. Owner reports cats have been treated on 25-sep-2019 and day after on 26-sep-2019, as fleas were still present. Additionally the owner reports the cats were treated again approximately 2 weeks later and some were treated again a few days after that. Minimal treatment interval according to the SPC is 4 weeks, thus the casts have been overdosed. Many fleas were present on the cats prior to first treatment. After last product administration on approximately 19-oct-2019, the owner reports he still found fleas on the cats on 21-oct-2019. It is unknown if the cats go outside or have contact with other animals. Cats are at least kept with 2 mature casts, but it is unknown if the cats are kept with other animals. Outcome of the reaction is not reported.
24-Oct-2019	UAE; 19NL000213; -; Netherlands	**Species:** Feline **Breed:** - **Sex:** U **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	21-Oct-2019	24-Oct-2019	3 Day(s)	D-D	As reported by animal owner, 4 cats, 6 to 8-month-old, unknown sex, breed and weight received FRONTLINE COMBO SPOT ON CAT, topical between the shoulder blades from the cat's owner once on 21-oct-2019. Fleas were present on the cats prior to treatment. After product administration on 24-oct-2019, the owner reports she still found fleas on the cats. The cats go outside. Unknown if they have contact with other animals. Unknown if the cats are kept with other animals. Outcome of the reaction is not reported.
31-Oct-2019	UAE; 19NL000214; -; Netherlands	**Species:** Feline **Breed:** - **Sex:** M **Sex qualifier:** -	4	4	4	**Product used:** FIPRONIL SPRAY **Other products**	12-Oct-2019	14-Oct-2019	<=24 hours	D-A	On 12 Ocober 2019 4 lively kittens (male, 5 weeks old, 400 grams) were treated with a small puff of the VMP because of fleas. On 14 October 2019, the kittens became weak, cold and paralysed. Within 6 hours after application, all 4 kittens died.

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ED_005739D_00014391-00170

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 5.00 Week(s) **Weight:** 0.4 kg				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					UPDATE from CA 23 November 2019: Additional information has been received from BI Animal Health BV: As reported by pet owner, 1 adult female mother cat, unknown age and weight and her 4 kittens, roughly 3 months old of unknown weight and sex, received FRONTLINE SPRAY expiry date and batch number unknown, by the cat's owner cutaneous on entire body on 12-oct-2019. Unknown dose on adult cat. 1 spray of 0.4 ml per kitten. After product administration, the owner reports 2 kittens died the next day on 13-oct-2019. The remaining 2 kittens died the day after, on 14-oct-2019. No other adverse reactions are reported for the 4 kittens, prior to death. Owner reports that the mother cat shows no adverse signs and previous litter of kittens from this mother cat was treated all summer with FRONTLINE SPRAY without adverse reactions occurring. 2 of the 4 kittens were taken for an autopsy. Autopsy was no longer possible on the other 2 kittens, once the event was reported on 16-oct-2019. The preliminary results from the autopsy show a pneumonia of bacterial or viral origin as the probable cause of death for both kittens that were examined. Case will be updated once full autopsy results and histology are available. Added "Other people" and "causality assessment of MAH". Changed "Exposed number","Reaction start date", "Reaction end date" and "Time to onset", according to the information received from the MAH.
25-Oct-2019	UAE; 19NL000217; -; Netherlands	**Species:** Canine **Breed:** - **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 4 - 6 kg	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Others)	18-Oct-2019	21-Oct-2019	3 Day(s)	D-D	As reported by animal owner, 2 dogs, weighing 4 and 6 kilos respectively, unknown age, breed, sex and of unknown reproductive status received FRONTLINE SPOT ON DOG S from the dog's owner once on 18-oct-2019 immediately after the dogs were trimmed and shampooed. Prior to treatment, fleas were present on the dogs. Fleas were still found on the dogs a few days after treatment. Product was used incorrectly according to the labelling, as dogs should not be washed 2 days before or after product application. Unknown if the dogs go outside, have contact with other animals or are housed with other animals. Outcome of the reaction is now reported.
31-Oct-2019	UAE; 19NL000221; -; Netherlands	**Species:** Canine **Breed:** Chihuahua **Sex:** X **Sex qualifier:** - **Age:** 1.50 Year(s) **Weight:** 2 - 3 kg	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Vlo Kill; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Concurrent use with other drug)	27-Oct-2019	31-Oct-2019	4 Day(s)	D-D	As reported by animal owner, 4 Chihuahua dogs, weighing between 2 to 3 kilos, 1,5 and 3 year old females and 3 and 16 year old males of unknown reproductive status received FRONTLINE COMBO DOG S from the dog's owner once on 27-oct-2019. A week earlier, the owner reports the dogs were treated with Vlo Kill on 20-oct-2019. Prior to both treatments, fleas were present on the dogs. Fleas were still found on the dogs a few days after treatment. Unknown if the dogs go outside, have contact with other animals or are housed with other animals. Outcome of the reaction is not reported.
01-Nov-2019	UAE; 19NL000222; -; Netherlands	**Species:** Feline **Breed:** Maine Coon Cat **Sex:** M **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products**	14-Nov-2018*	28-Oct-2019	8 Day(s)	D-D	As reported by pet owner, male neutered Maine Coon Cat, 5 years old weighing 4,5 kilos received FRONTLINE COMBO CAT, from the cat's owner for a long time. Latest application was on 20-oct-2019. Prior to last treatment no fleas were reported on the cat. After product administration, on 28-oct-2019, the owner reports fleas on the cats as found by the veterinarian during the yearly checkup and vaccination visit. Veterinarian prescribed Advantage

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ED_005739D_00014391-00171

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 5.00 Year(s) **Weight:** 4.5 kg				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					80 for the cat, which was administered on 01-nov-2019. The cat goes outside and has regular contact with other animals. Unknown if the cat is kept with other animals. Final outcome of the reaction is not reported.
01-Nov-2019	UAE; 19NL000223; -; Netherlands	**Species:** Feline **Breed:** Persian (No Further Description) **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 2 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Oct-2019	01-Nov-2019	4 Day(s)	D-D	As reported by pet owner, female neutered Persian cat, 11 years old weighing 2 kilos received FRONTLINE COMBO CAT, from the cat's owner once on 28-oct-2019. Prior to treatment fleas were present on the cat. Cat had been treated monthly with Comfortis until aug-2019 and fleas are suspected to be present from sep-2019 onward. After Frontline product administration the owner still reports fleas on the cat starting on 01-nov-2019. Owner reports that due to the fleas, the cat scratches a lot causing bald spots and broken skin. The cat does not go outside. The cat is housed with 2 dogs, which have the same flea treatment regime and also still have fleas. Unknown if cat has contact with other animals. Final outcome of the reaction is not reported.
01-Nov-2019	UAE; 19NL000224; -; Netherlands	**Species:** Canine **Breed:** Keeshond **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 25 - 30 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Oct-2019	01-Nov-2019	4 Day(s)	D-C	As reported by pet owner, Husky dog, 25-30 kg, unknown age and sex received FRONTLINE COMBO DOG L, from the dog's owner once on 28-oct-2019. Prior to treatment fleas were present on the dog. Dog had been treated monthly with Comfortis until aug-2019 and fleas are suspected to be present from sep-2019 onward. After Frontline product administration the owner still reports fleas on the dog starting on 01-nov-2019. The dog goes outside. The dog is housed with 1 other dog and 1 cat, which have the same flea treatment regime and also still have fleas. Unknown if dog has contact with other animals. Final outcome of the reaction is not reported.
01-Nov-2019	UAE; 19NL000226; -; Netherlands	**Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** 7 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	31-Oct-2019*	01-Nov-2019	1 Day(s)	D-C	As reported by pet owner, a 9 month old female Maltese Jack-Russel Terrier mixed breed dog weighing 7 kilos of unknown reproductive status received FRONTLINE COMBO DOG S expiry date and batch number unknown cutaneous between the shoulder blades from the dog's owner once on 31-oct-2019. Day after product administration the dog reacted by stretching her limbs unusually while walking. Dog was never treated against fleas or ticks before. Veterinarian was not consulted. Outcome of the reaction has not been reported.
01-Nov-2019	UAE; 19NL000227; -; Netherlands	**Species:** Canine **Breed:** - **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 9 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	28-Oct-2019	31-Oct-2019	3 Day(s)	D-D	As reported by animal owner, a 2 year old female neutered dog weighing 9 kilos of unknown breed received FRONTLINE COMBO DOG S expiry date and batch number unknown cutaneous between the shoulder blades from the dog owner once on 28-oct-2019. There were at least 10 fleas present on the dog prior to treatment. 3 days after product administration, on 31-oct-2019, the attending veterinarian found 10 fleas on the dog. Veterinarian prescribed Bravecto, which was administered on 31-oct-2019.

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ED_005739D_00014391-00172

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** Unknown to Company					Outcome of the reaction is not reported. The dog is housed with a cat, that goes outside, of unknown flea infection and flea treatment status. It is unknown if the dog goes outside or has contact with other animals.
21-Nov-2019	UAE; 19NL000231; -; Netherlands	**Species:** Feline **Breed:** - **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** Seresto 1,25 g + 0,56 g halsband voor katten; **Route:** - **Was the product used ok?:** Unknown to Company	2019	2019*	4 Day(s)	D-B	On 26 Oct-2019, 4 days before 30-Oct-2019, the owner applied a Seresto collar to a cat of unknown breed, sex, age and weight. It is unknown if Seresto was used before. In the past, prior to the treatment with Seresto (date unknown) the cat was treated with 'Frontline'. Four days after the application of 'Frontline' (date unknown) the cat had a severe epileptic seizure. On 30-Oct-2019, the cat had again an epileptic seizure. The collar was removed after the signs. It is unknown if the cat has recovered. The owner has another cat with a Seresto collar. It is unknown if this cat showed any reaction. 21- 11-19 CA: the following fields have been changed or filled in: Frontline: treatment end date, authorization holder/company, animal suspect substance Reason for Treatment: Prevention State of health at time of treatment: unknown
07-Nov-2019	UAE; 19NL000232; -; Netherlands	**Species:** Feline **Breed:** Burmese **Sex:** M **Sex qualifier:** - **Age:** 3.00 Year(s) **Weight:** 5 kg	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** Seresto collar; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	30-Jun-2019	06-Nov-2019	3 Day(s)	D-D	As reported by pet owner, 2 male Burmese cats, 3 years old, weighing 5 kilos of unknown reproductive status received FRONTLINE SPOT ON CAT expiry date and batch number unknown, by the cat's owner cutaneous between the shoulder blades for 4 months with 4 weeks in between. First product application was approximately 30-jun-2019 and latest application on 03-nov-2019. Cats had a Seresto collar since Mar-2019, but owner still repots fleas on the cats in Jun-2019. Thus FRONTLINE application was started together with the Seresto collar. Seresto collar was taken of the animals 01-nov-2019. After last FRONTLINE product administration, the owner reports she still found fleas on the cats on 06-nov-2019. Cats go outside. The cats are not housed with 2 dogs with the same treatment schedule and same flea status. It is unknown if the cats have contact with other animals. Outcome of the reaction is not reported.
07-Nov-2019	UAE; 19NL000233; -; Netherlands	**Species:** Canine **Breed:** Dutch Sheepdog **Sex:** F **Sex qualifier:** - **Age:** 5.00 Year(s) **Weight:** 17 - 24 kg	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** Seresto collar; FIPRONIL SPOT ON DOG; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	30-Jun-2019	06-Nov-2019	3 Day(s)	D-D	As reported by pet owner, 2 female Dutch Sheepdogs, 5 and 11 years old, weighing 17 and 24 kilos of unknown reproductive status received FRONTLINE SPOT ON DOG M and L respectively, expiry date and batch number unknown, by the dog's owner cutaneous between the shoulder blades for 4 months with 4 weeks in between. First product application was approximately 30-jun-2019 and latest application on 03-nov-2019. Dogs had a Seresto collar since Mar-2019, but owner still repots fleas on the dogs in Jun-2019. Thus FRONTLINE application was started together with the Seresto collar. Seresto collar was taken of the animals 01-nov-2019. After last FRONTLINE product administration, the owner reports she still found fleas on the dogs on 06-nov-2019. Dogs go outside. The dogs are housed with 2 cats with the same treatment schedule and same flea status. It is unknown if the dogs have contact with other animals. Outcome of the reaction is not reported.
07-Nov-2019	UAE;	**Species:** Canine	1	1	0	**Product used:**	01-Oct-2013*	24-Oct-2019*	23 Day(s)	D-D	As reported by pet owner, a 7 year old female Lhasa Apso dog

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ED_005739D_00014391-00173

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19NL000234; -; Netherlands	**Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 8 kg				FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					weighing 8 kilos of unknown reproductive status received FRONTLINE COMBO DOG S, batch number and expiry date unknown, cutaneous between the shoulder blades from the dog's owner for 6 years every month, latest product administration on 01-oct-2019. On approximately 24-oct-2019 the owner reports over 20 fleas on the dog. It is unknown if the dog goes outside. It is unknown if the dog is housed with other animals. Outcome of the reaction is not reported.
07-Nov-2019	UAE; 19NL000235; -; Netherlands	**Species:** Feline **Breed:** European **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	04-Nov-2019	04-Nov-2019	0 Day(s)	D-D	As reported by pet owner, 1 European cat, unknown age, sex and weight of unknown reproductive status received FRONTLINE COMBO CAT from the cat's owner once on 04-nov-2019 after cat was adopted from a shelter 2 weeks earlier. Fleas were present on the cat prior to treatment. Animal owner reports she still found fleas on the cat until 06-nov-2019. Cat is kept with 2 dogs, no fleas found on the dogs. Cat does not go outside. Unknown if the cat has contact with other animals. 07-nov-2019 owner reports no more fleas on the cat.
19-Nov-2019	UAE; 19NL000237; -; Netherlands	**Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** - **Age:** 1.00 Year(s) **Weight:** 5 kg*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	19-Nov-2019*	20-Nov-2019*	N/A	D-D	Owner saw fleas on cat around 18 nov 2019 and treated cat with Frontline Combo. Day after treatment owners still saw fleas on the cat, and this was perceived as a suspected lack of efficacy . Owner only uses the product when she sees fleas on the cat, never preventively. Owner has been explained at 22 november about the flea life cycle and that product efficacy cannot be expected after 24 hours after treatment.
14-Nov-2019	UAE; 19NL000239; -; Netherlands	**Species:** Canine **Breed:** - **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 9.8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	08-Nov-2019	1 Week(s)	D-D	As reported by animal owner, a 6 year old female neutered dog weighing 9,8 kilos of unknown breed received FRONTLINE COMBO DOG S expiry date and batch number unknown cutaneous between on the neck and back from the dog's owner on 01-nov-2019. No fleas were present on the dog prior to treatment. 1 week after product administration, on 08-nov-2019, the owner reports fleas on the dog. Owner administered Stronghold on 14-nov-2019. The dog is housed with 2 cats and a horse, all of unknown flea infection and flea treatment status. It is unknown if the dog goes outside or has contact with other animals. Final outcome of the reaction is not reported.

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ED_005739D_00014391-00174

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
13-Nov-2019	UAE; 19NL000240; -; Netherlands	**Species:** Feline **Breed:** European **Sex:** U **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 1.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Route not indicated / recommended)	13-Nov-2019	14-Nov-2019	1 Day(s)	D-D	As reported by animal owner, European cat, 4 months old weighing 1,5 kilos of unknown sex and reproductive status received FRONTLINE COMBO CAT, from the cat's owner once on 13-nov-2019. Owner reports the product was administered on the hairs, instead of on the skin, thus product was not applied according to the SPC. Prior to treatment fleas were present on the cat. After product administration the owner still reports finding 4 fleas on the cat per day between 14-nov-2019 and 19-nov-2019. The cat does not go outside. Unknown if cat has contact with other animals. Final outcome of the reaction is not reported.
02-Dec-2019	UAE; 19NL000241; -; Netherlands	**Species:** Feline **Breed:** - **Sex:** M **Sex qualifier:** Neutered **Age:** 15.00 Year(s) **Weight:** 5.8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	03-Jun-2018*	08-Jun-2018*	5 Day(s)	D-D	As reported by animal owner, 1 male neutered cat, 15 years old weighing 5,8 kilos of unknown breed received FRONTLINE COMBO CAT, from the cat's owner on approximately 03-jun-2018. Product was administered topically between the shoulder blades. Within 1 week after product administration, the owner reports a bald spot at the application site. The owner reports the cat recovered fully, unknown time after event.
29-Nov-2019	UAE; 19NL000242; -; Netherlands	**Species:** Feline **Breed:** Ragdoll **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	05-Nov-2019	29-Nov-2019	9 Day(s)	D-D	As reported by animal owner, male neutered Ragdoll cat, 3 years old and weighing 6 kilos received FRONTLINE COMBO SPOT ON CAT, from the cat's owner on 05-nov-2019 and 20-nov-2019 topically between the shoulder blades. The animal was overdosed, as 4 weeks is the minimal treatment interval according to the SPC. There were fleas present on the cat before treatment. 9 days after last product administration, on 29-nov-2019, the owner reports there were still fleas on the cat. The cat was treated with Vectra 3D on 29-nov-2019 as prescribed by the veterinarian. Cat does not go outside. Unknown if the cat is housed or has contact with other animals. Final outcome of the event is not reported.
02-Dec-2019	UAE; 19NL000243; -; Netherlands	**Species:** Feline **Breed:** - **Sex:** U **Sex qualifier:** - **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** - **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by pet owner, 1 cat, unknown sex, age and weight of unknown reproductive status received FRONTLINE unsubstantiated which exact product, by the cat's owner at unknown date and unknown frequency and dose. Animal owner reports hair loss unreported time after product application. Outcome of the reaction is not reported.

N/A signifies the information for this field is either not available or not applicable

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* indicates Approximate date or weight.

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ED_005739D_00014391-00175

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
16-Dec-2019	UAE; 19NL000247; -; Netherlands	**Species:** Feline **Breed:** British Shorthair **Sex:** U **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** Comfortis 140 mg chewable tablets for dogs and cats; **Route:** unknown **Was the product used ok?:** Unknown to Company	17-Nov-2019	19-Nov-2019	N/A	D-B	On 27 Nov 2019, attending veterinarian contacted Elanco to report adverse events in a neutered Bristish shorthair feline, 14 years old, weighing 3 kgs, unknown sex and medical condition after administration of Comfortis tablet for flea infestation. The cat had a concomitant medical condition of heart murmur. On 17 Nov 2019, the cat had been administered fipronil. On 19 Nov 2019, animal owner administered one tablet of Comfortis 140 mg to the cat, unknown if according to label or for the first time. Two and a half hour post product administration, the cat exhibited epileptic convulsions. On 23 Nov 2019, the cat is still experiencing less severe convulsions. Unknown if any medical treatment was provided. Elanco considers this case closed. Additional information will be filed as received. 16-12-19 CA: the following fields have been changed or filled in: Breeds, time to onset, Comfortis:dosage form, authorization holder/company, ATC veterinary code, Frontline: characterization, authorization holder/company. VedDRA term seizure NOS changed into epileptic seizure according to information provided in the case narrative. 2019.12.19 MAH assessment fipronil product is UNKNOWN is changed into frontline spot on cat as an example of an often used product. [Reason for use for product: Generic: Spinosad Brand: Comfortis 140 mg Reason: flea infestation Generic: Fipronil Brand: Frontline (cats) Reason: Unknown.] [State of health: Unknown]
17-Dec-2019	UAE; 19NL000249; -; Netherlands	**Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** - **Age:** 11.00 Week(s) **Weight:** 1.3 kg	3	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Dec-2019	01-Dec-2019	<=24 hours	D-C	Suspected adverse reaction. On 1 December 2019, 3 kittens were administered the VMP (dosage unknown) topically by the animal owner. Same day one of the kittens (European, 11 weeks old) experienced severe tremors continuously and had abnormal behaviour/aggression leading to hyperthermia. The reaction lasted several hours.
12-Dec-2019	UAE; 19NL000253; -; Netherlands	**Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 4 kg	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Nov-2019	08-Dec-2019	5 Week(s) 2 Day(s)	D-A	Suspected adverse event: as reported by owner the cat (European short hair, a neutered female, 13 years old, 4 kg) received on 01nov2019 1 pipet of Frontline Combo Cat (Batch T40113AW expiry date 01dec2021) on the skin between the shoulder blades by the owner. According to the owner no fleas were seen previously. Previous flea treatment was 01sep2019 with a pipet of Stronghold for cats. The cat lives indoors, the other cat of the household goes outside, as is the dog of the family. Both the dog and the other cat also received 1 pipet of Frontline combo on 01nov2019 suitable for weight and species and applied according to the leaflet by owner. On 08dec2019 the dog (Belgian Shepherd) had bitten the cat in a fight. No (external) blood or lesions were found by the owners. The owners noticed that the cat became dull

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ED_005739D_00014391-00176

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											and they found living fleas on the cat. The owners applied 1 pipet Stronghold for cats (batch and expiry unknown) according to leaflet on the cat on 09dec2019. The cat didn't improve. The owners brought the cat to a veterinary clinic on 11dec2019. On the physical examination the cat was hypothermic (32 degrees Celsius), anemic (very pale mucosae), dull and living fleas were found. No blood- or ultrasound exam was done. The cat was treated symptomatically with subcutaneous fluids and they tried to warm her externally. Initially the cat improved but on 12dec2019, the situation worsened and the owners decided together with the veterinarian to euthanize the cat.
21-Dec-2019	UAE; 19NL000256; -; Netherlands	**Species:** Feline **Breed:** - **Sex:** U **Sex qualifier:** - **Age:** - **Weight:** 4 - 6 kg	4	4	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	30-Nov-2017*	21-Dec-2019*	3 Week(s)	D-D	As reported by pet owner, 4 cats: a 6 kilo British Shorthair, a 5 kilo Persian and 2 European Shorthairs weighing 4 kilos, unknown age, of unknown reproductive status received FRONTLINE SPOT ON CAT expiry date and batch number unknown, by the cat's owner cutaneous between the shoulder blades for a few years each month. First product application date unknown. Latest application was on approximately 30-nov-2019. Owner repots fleas on the cats on approximately 21-dec-2019, 3 weeks after latest product application. European Cats go outside, the others do not. It is unknown if the cats have contact with other animals. Owner started using Vectra Felis and reports seeing almost no more fleas on the cats. Final outcome of the reaction is not reported.
30-Dec-2019	UAE; 19NL000257; -; Netherlands	**Species:** Canine **Breed:** Spaniel (King Charles) **Sex:** M **Sex qualifier:** - **Age:** 6.00 Year(s) **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	25-Nov-2015	16-Dec-2019	3 Week(s)	D-D	As reported by animal owner, a 6 year old male King Charles Cavalier Spaniel dog weighing 8 kilos of unknown reproductive status received FRONTLINE COMBO DOG S expiry date and batch number unknown cutaneous between the shoulder blades from the dog owner for 4 years every 4 weeks, latest administration on 25-nov-2019. 3 weeks after latest product administration, on 16-dec-2019, the animals owner reports the dog itching and fleas on the dog. The owner administered the product again on 16-dec-2019, which is an overdose according to the SPC, as the minimal treatment interval is 4 weeks. Owner consulted a veterinarian who prescribed an unspecified anti allergy tablet for the itch. The veterinarian assumed the itching was due to the fleas, not due to the treatment. Final outcome of the reaction is not reported. It is unknown if the dog is housed with other animals, goes outside or has contact with other animals.
11-Oct-2019	UAE; 19NZ000211; -; New Zealand	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** - **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	06-Sep-2019	06-Sep-2019*	N/A	D-D	As reported by the owner, FRONTLINE PLUS for cats, batch and expiry unknown, was applied to a 4kg female neutered domestic shorthair cat on 6 Sep 2019 and again on 6 Oct 2019, for flea treatment. The owner reports the cat has been scratching and has seen some live fleas, although was unsure how many. There are no other pets in the household. The cat has outdoor access. The owner advised she was using FRONTLINE PLUS prior to the treatment on 6 Sep 2019 but the dates of this were unclear.
07-Oct-2019	UAE; 19NZ000220; -; New Zealand	**Species:** Feline **Breed:** Domestic Shorthair	1	1	0	**Product used:** FIPRONIL 10%/S	22-Sep-2019	24-Sep-2019	2 Day(s)	D-D	At told to me by the owner, on 22 September 2019, she applied Frontline Plus for Cats (FLP), batch and expiry unknown, package unavailable, to her 3 year-old, 6kg, male neutered, DSH cat Ziggy.

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ED_005739D_00014391-00177

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		(Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 6 kg				METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					Two days later on 24 Sept 2019 the owner noticed a patch of hair missing at the site of application. The cat is not scratching at site and is otherwise behaving normally. This is the first time the product has been using on this cat. Has used Bravecto Plus previously with no adverse reaction.
07-Oct-2019	UAE; 19NZ000221; -; New Zealand	**Species:** Feline **Breed:** Persian (No Further Description) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 3.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	23-Sep-2019	23-Sep-2019	N/A	D-D	As reported by the owner, she treated her cat with Frontline Plus for cats (FLP), batch and expiry unknown, on approximately 23 September 2019 and then again on 30 Sept 2019 because she continued to see fleas on the cat and a few jumping onto her young baby. There is only one cat in the household, Lola, a 6 year old, 3.5kg, female spayed Persian who has been scratching and licking and getting bald patches between front legs and chest. This has continued despite the applications of FLP and the owner feels the product is not working. Generally Broadline or Advantage is used on this cat, although the owner is unable to recall dates of previous treatments but it was at least several weeks prior.
07-Nov-2019	UAE; 19NZ000229; -; New Zealand	**Species:** Feline **Breed:** - **Sex:** U **Sex qualifier:** Unknown **Age:** Unknown **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	09-Oct-2019*	11-Oct-2019*	2 Day(s)	D-D	As reported to me by a pet store manager, a client returned a 6-pack of Frontline Plus for Cats, Batch S40211AW, expiry 12/2020 (FLP), with five remaining pipettes after her cat had a patch of hair loss at the application site a few days after applying the product. The skin at the site was reported to have been a little red at the time, but no veterinary treatment was required and the cat is fine now with the hair growing back. The exact date of application is unknown but given the description to the store manager, it is approximately one month ago (9 October 2019). The manager did not get any details of the cat or the owner and therefor this is the extent of the information available.
12-Nov-2019	UAE; 19NZ000231; -; New Zealand	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	22	22	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	13-Oct-2019*	12-Nov-2019*	30 Day(s)	D-D	As reported by the owner, FRONTLINE PLUS for dogs 10-20kg, batch and expiry unknown, was used to treat 22 dogs owned by a dog breeder. The breeder was unsure of the dogs ' weights and treatment dates but advised they were all treated on different dates. The product was purchased on 3 Aug 2019 but the breeder thinks she treated quite recently. At the time of reporting, the owner was seeing 'lots' of fleas on the dogs but was unsure of exact numbers. She had not used a flea treatment prior to FRONTLINE PLUS application for an extended period of time.

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ED_005739D_00014391-00178

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
18-Nov-2019	UAE; 19NZ000234; -; New Zealand	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 5 kg*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Sep-2019	28-Sep-2019	1 Day(s)	D-D	As reported by the office manager, FRONTLINE PLUS for cats, batch S40716AW exp 05.2021, was applied to an approximately 5 kg, 10 year old female cat, on 27 Sept 2019 by the owner. The owner reported that the next day application site alopecia was noted. Two to three days after application, the cat had 'a couple' of vomits for another two to three days, and was lethargic. No veterinary care was sought and the cat recovered after this time. The cat has previously experienced application site alopecia after application of Frontline Plus but the owner felt it was worse on this occasion, and has not experienced vomiting previously. It is unknown if the cat licked the application site. The cat has previously had Frontline Plus applied 6 weekly or only as required.
19-Nov-2019	UAE; 19NZ000235; -; New Zealand	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-May-2019*	19-May-2019*	N/A	D-D	As reported by the owner, FRONTLINE PLUS for cats, batch S40912BW exp 06.2021, was applied to an approximately 2 year old female cat called Trevor by the owner, last treatment date approximately 12 Nov 2019. At the time of reporting, the owner was seeing 2 to 3 small fleas on the cat. Trevor was a stray cat and was not flea treated on entry to the house. The owner describes household members being bitten extensively prior to beginning a flea treatment program for Trevor. For the first few months, the owner used a different flea treatment product (brand unknown) on Trevor and was still seeing many fleas. She started using Frontline Plus approximately 6 months ago and has used it monthly. She has had the house flea bombed. Members of the household are still being bitten. There are no other pets in the household.
20-Nov-2019	UAE; 19NZ000236; -; New Zealand	**Species:** Canine **Breed:** Retriever (Labrador, Chocolate) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 31.7 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Nov-2019	16-Nov-2019*	4 Day(s)	D-C	As reported by the owner, FRONTLINE PLUS for dogs 20 – 40kg, batch S61304AR exp 04 2021, was applied to 'Bailey' a 31.7kg chocolate Labrador neutered female dog, on 12 Nov 2019 by the owner. On 16 Nov 2019 Bailey presented to the vet clinic with two large hot spots that had developed where the FRONTLINE PLUS was applied. She had been scratching that morning. She was eating, drinking and toileting normally and no change was noted in her demeanour. On examination, two skin lesions approximately 3cm in diameter were noted in her shoulder region. The vet clipped and cleaned the shoulder area, and the dog was treated with 1ml of dexadresson (MSD animal health dexamethasone), 600mg cephalexin tablets BID PO, 20mg prednisone SID q 4 days then EOD until finished, and Elocon (mometasone) lotion to be applied twice daily. At the time of reporting, the owner advised that one lesion was healing well but one was taking longer. The vet listed pyotraumatic dermatitis, reaction to FRONTLINE PLUS, FAD and other as differential diagnoses. The dog had not been treated with a topical flea product previously.
03-Dec-2019	UAE; 19NZ000243; -; New Zealand	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 34.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	12-Nov-2019	12-Nov-2019	0 Day(s)	D-D	As reported by the owner, FRONTLINE PLUS for Large Dogs 20-40 kg, batch F63102AX, exp 09 2021, was applied to a male 9 year old, 34.5 kg, German Shephard cross called Daemon on approximately 12 Nov 2019. The owner reports the dog has been scratching a lot (this had started prior to Frontline Plus application), and he is finding 50 to 60 live fleas on the dog each day. The owner is washing the dog daily to every third day due to the fleas, although did not wash the dog for a week after the treatment was applied. Previous treatments with Frontline Plus are estimated to be monthly, although exact dates are unclear and he was overdue for treatment at the time of the latest application. Other members

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ED_005739D_00014391-00179

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						product used ok?: Yes					of the household are being bitten. There are two cats in the household that are treated with Frontline Plus and the owner has not noticed fleas on these cats. He has not previously noted fleas on the dog. The dog has developed a dermatitis over its back and has an appointment with a veterinarian.
11-Dec-2019	UAE; 19NZ000250; -; New Zealand	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 5.85 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Nov-2019*	30-Nov-2019*	2 Week(s)	D-D	As reported by the owner, FRONTLINE PLUS for cats, batch and expiry unknown, was applied to a 5.85kg 6 year old domestic short hair female cat 'Kitty' by the owner on approximately 16 Nov 2019. Two to three weeks later, the owner noticed a healing scab at the application site, approx 2cm in diameter. The cat was otherwise well and the lesion has completely healed at the time of reporting. The cat has not had FRONTLINE PLUS applied previously, but has had other topical products with no noted reaction.
29-Oct-2019	UAE; 19PL000035; -; Poland	**Species:** Canine **Breed:** Canine Other **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 12 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Prac-tic 12.5% 1.1 ml; **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2019*	27-Sep-2019	N/A	D-B	On 1 Oct 2019, Elanco was contacted regarding adverse event in a 2 year old female 12 kg dog while treated with Prac-tic 12.5% 1.1 ml. On an unknown date (approximately captured as 1 Jul 2019 for reporting purpose) the dog received Prac-tic 12.5% 1.1 ml. On 27 Sep 2019, at 11 pm. The first sign occurred before midnight at 12 pm the dog showed convulsion, tremors (cumulatively coded as Convulsion), stiffness and the body temperature increased (40,5°C) The dog was attended in the vet practice in the night and was hospitalized next day. on 28SEP2019 the dog was still apathetic and drowsiness (lethargy) and vomiting were observed. The dog is still under treatment, it did not recovery completely. The laboratory tests showed leukocytosis and hemolysis (captured as abnormal test result) and RTG of abdomen were done. The dog was treated by attending vet (unknown details). Elanco considers this case closed. Follow up information will be added if provided. [Reason for use for product: Generic: pyriprole Brand: Prac-tic 12.5% 1.1 ml Reason: Unknown Generic: Fipronil Brand: Frontline Reason: Unknown.] [State of health: Unknown]
26-Oct-2019	UAE; 19SE000183; -; Sweden	**Species:** Canine **Breed:** - **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2019*	Oct-2019*	N/A	D-D	As reported by a pharmacist, a dog (age, breed, gender, body weight unknown) was treated with FRONTLINE VET 100 MG/ML SPOT-ON FOR DOGS (SIZE L) (lot S20418AR, exp FEB-2020, valid) administration details not further specified, for tick control. The dog received FRONTLINE at two occasions according to label (as reported by the animal owner to the pharmacist) but the dog had a lot of ticks. MAH tried to contact the owner for more information without success.

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ED_005739D_00014391-00180

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
01-Oct-2019	UAE; 19UK003312; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the staff member at the retail outlet, approximately one canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG S) (Batch S21906AL expiry NOV 2021) (details unknown) for an unknown indication. The animal owner said to the retail outlet that the FRONTLINE is not working. They swapped from Advantage to FRONTLINE but has since gone to the vets for a stronger product. The animal owner said that it does not work and their dogs have more fleas and they are not going away. Start date added for submission purposes only.
01-Oct-2019	UAE; 19UK003313; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the staff member at the retail outlet, approximately one canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M) (Batch S2122AW expiry AUG 2021) (details unknown) for an unknown indication. The animal owner said to the retail outlet that the FRONTLINE is not working. They swapped from Advantage to FRONTLINE but has since gone to the vets for a stronger product. The animal owner said that it does not work and their dogs have more fleas and they are not going away. Start date added for submission purposes only.
01-Oct-2019	UAE; 19UK003314; Leicestershire; United Kingdom	**Species:** Canine **Breed:** Airedale Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 20 - 40 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL SPOT ON DOG; FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Aug-2019	22-Aug-2019	N/A	D-D	As reported by the retail outlet, a canine (signalment otherwise unknow) was administered FRONTLINE PLUS SPOT ON DOG L (batch R61517AR expiry JUN 2020) (details unknown) by the animal owner monthly for an unknown indication. The retail outlets staff member reports that it is the right product for the animal's weight and the owner has been applying 1 per month, but the dog still has fleas. The animal owner has treated the house also. Start date added for submission purposes only. UPDATE 10 OCT 2019: The animal is Rupert, a 10 year old male neutered Airedale Terrier canine, weighing 20-40 kg and in good condition. The product was applied topically to an unknown site, at a dose of 1 dose monthly, from 22 AUG 2019 for an unknown indication. The animal has always used FRONTLINE (assumed FRONTLINE SPOT ON DOG L) (batch and expiry unknown) and then FRONTLINE PLUS. The animal has never had fleas and the animal owner has been applying the products monthly for a long time as required. The most recent batch was purchased in AUG 2019 and then the animal got fleas and this led to a home infestation. A second dose was applied on 24 SEP 2019. The animal owner was due to treat the animal this month and has since spoken to the vet and moved to another treatment, Bravecto. The staff at the retail outlet as well as the vet and dog groomer have all told the animal owner that FRONTLINE is no longer effective, and the vets have said that they can no longer recommend FRONTLINE as part of flea treatment. The animal owner has spent a lot of money on the FRONTLINE range and would like a refund for one FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch and expiry unknown) and a three pack of FRONTLINE PLUS. The animal owner is adamant that the product is no longer working as they haven't had a problem before and they haven't done anything different in terms of treatment.
01-Oct-2019	UAE; 19UK003315; -; United Kingdom	**Species:** Canine **Breed:** Canine	2	2	0	**Product used:** FIPRONIL	N/A	23-Sep-2019*	0 Day(s)	D-D	As reported by the animal owner, two canines (signalment otherwise unknown) were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M) (batch and

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ED_005739D_00014391-00181

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		(unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					expiry unknown) (details unknown) by the animal owner last week (estimated 23 SEP 2019) for an unknown indication. The animal owner reports that they treated both dogs last week with no result and asks if it is ok to treat them with FRONTLINE PLUS again this week.
01-Oct-2019	UAE; 19UK003317; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	29-Sep-2019	1 Day(s)	D-C	As reported by the animal owner, a male feline (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch s21715al and expiry OCT 2021) (details unknown) topically to the neck by the animal owner on 28 SEP 2019 for an unknown indication. The animal owner reports that they put the FRONTLINE on their male cat's neck and it has burnt him severely. The poor cat has a large burn on his neck now, which the animal owner saw the next day. It was red and sore. The animal owner did not contact their vet as they have various topical creams to apply due to having a smallholding with animals and so has lots of medications. The product was purchased online and obviously the animal owner now cannot use the other pipettes on their cat, and it was a waste of money and their poor cat has a burn.
01-Oct-2019	UAE; 19UK003319; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL SPOT ON CAT; Acclaim; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	01-Oct-2019	4 Week(s)	D-D	As reported by the animal owner, a male cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), route and frequency unknown, administered by the cat's owner 4 weeks ago (date of administration estimated as 03 SEP 2019). Two weeks later (date estimated as 17 SEP 2019) the owner treated the cat with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), route and frequency unknown. A week after this date on 01 OCT 2019 the owner reported that the cat still had fleas. The owner reported that the cat did go outside and the cat was not totally infested in the first place, but the fleas were still there. The owner had also treated the house with Acclaim spray and vacuumed the house.
02-Oct-2019	UAE; 19UK003322; -; United Kingdom	**Species:** Canine **Breed:** Spaniel **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** Bob Martin Clear; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	01-Oct-2019*	N/A	D-D	As reported by the animal owner, two Spaniel canines (signalment otherwise unknown) were given FRONTLINE SPOT ON (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) by the animal owner (no further details available). The animal owner reports that the dogs have had fleas for 3 months now, the animal owner has used Bob Martin Clear and also FRONTLINE SPOT ON to no effect. They animal owner is still combing fleas off them every day, they spray their furniture every night (product unknown) and the dogs' beds every morning and vacuum every day. Start date for submission purposes only.
02-Oct-2019	UAE; 19UK003328; County Durham; United Kingdom	**Species:** Canine **Breed:** Small crossbred (<10 Kg)	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products**	26-Aug-2019	26-Aug-2019*	N/A	D-D	As reported by the animal owner, Hollie a 4 year old, intact female Pug crossbred dog, weighing 7.5 kg and of good health, was treated with FRONTLINE SPOT ON DOG S (batch number: T20305AL and expiry date: DEC 2021) at a dose of 1 dosage form,

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ED_005739D_00014391-00182

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** 7.5 kg				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					applied topically, once a month, started on 26 AUG 2019, administered by the animal's owner, as preventative care. The owner reported that since using this product the fleas are attracted to her dog, the owner was always seeing live fleas, the product was not working. As a result the owner has also got a home infestation. The owner only moved onto this product after using a different brand that was prescribed by her vet. The owner had used this product a couple of years ago.
03-Oct-2019	UAE; 19UK003339; West Glamorgan; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately 2 felines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch S41303AW expiry OCT 2021) (details unknown) by the animal owner, for an unknown indication. The animal owner reports that they are disappointed in the product. They have always used FRONTLINE on their cats and dogs but this latest purchase didn't work at all. In fact for some reason their cats are scratching more and still have fleas. The animal owner wouldn't mind paying the money if it worked, but it was a total waste of money. The animal owner now has to buy a different product to treat their cats. Start date added for submission purposes only.
03-Oct-2019	UAE; 19UK003340; Cheltenham; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a female canine (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON DOG M (batch and expiry unknown, details unknown) for an unknown indication. The animal owner felt that they just had to write and express their complete disappointment and anger after purchasing the product. It has had no effect at all on their dog, even though they used the correct dosage. The is still lousy and crawling with fleas. The animal is still sratching away, and has a white coat and so they animal owner can see fleas all over her. The animal owner also just found a tick on her from their walk the other day in long grass. Start date added for submission purposes only.
03-Oct-2019	UAE; 19UK003342; -; United Kingdom	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** M **Sex qualifier:** - **Age:** 13.00 Year(s) **Weight:** 10 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	19-Sep-2019*	19-Sep-2019	N/A	D-D	As reported by the animal owner, Jack, a 13 year old male intact Jack Russell Terrier canine, weighing 10 kg and in unknown condition was administered FRONTLINE PLUS SPOT ON DOG S (batch R6082S expiry unknown) topically to an unknown site, by the animal owner, at a dose of 1 dose two weeks ago (19 SEP 2019) and again yesterday (02 OCT 2019) as they saw fleas. The animal is prone to seizures but is not on any medication. The animal owner is still seeing a few fleas on the pet and thinks that the product might not be working. There are a lot of eggs near his tail and the animal owner is also being bitten. The animal owner believes that the number of fleas is going down but they are still seeing them. No flea treatment has been used for the animal prior to two weeks ago. The animal owner is going to persevere.
03-Oct-2019	UAE; 19UK003343; Avon; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE	N/A	2019*	N/A	D-D	As reported by the retail outlet staff member, approximately 2 canines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON DOG M (batch S63204 expiry OCT 2021, details unknown) for an unknown indication. The animal

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ED_005739D_00014391-00183

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					owner reported to the staff member that this is the first time that they have used the product and that they usually use a different brand. As it stands, the FRONTLINE PLUS product has neither worked nor solved the issue for the animal owner themselves or their pets, and they now therefore have to spend more money rectifying the issue and purchase more treatment. The product has not solved the issue of their pets still having large and small fleas, and not just a couple, still the same amount in large numbers. The product has not done what it advertises it does. The product has been unsatisfactory and they wish to be refunded. Start date added for submission purposes only.
04-Oct-2019	UAE; 19UK003350; -; United Kingdom	**Species:** Feline **Breed:** Siberian Cat **Sex:** X **Sex qualifier:** Mixed **Age:** 3.00 Year(s) **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Oct-2018*	2019*	N/A	D-D	As reported by the animal owner, Miko, a male intact and Elsa a female neutered, both 3 year old Siberian Cat felines, of unknown weight and in good condition were administered FRONTLINE PLUS SPOT ON CAT (batch S40812A expiry JUN 2020) topically to an unknown site, by the animal owner, at a dose of 1 dose monthly, from a year ago (OCT 2018) for parasite control, part of their monthly treatment. The animal owner does not know how much the animals weigh, but states that the male is quite large in size and the female is normal size. The animal owner has been using the product for about a year and doesn't understand why it is not working. There are around 15 fleas on each cat being seen and the animal owner is being bitten. The animal owner admits that they had a few gaps in treatment about 2 months ago. The animal owner is washing bedding on a hot wash, using FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch and expiry unknown) and hoovering etc. Start date added for submission purposes only.
04-Oct-2019	UAE; 19UK003356; -; United Kingdom	**Species:** Feline **Breed:** Feline various breeds **Sex:** X **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Oct-2018*	04-Oct-2019	N/A	D-D	As reported by the owner 4 cats (Jess a 6 year old, female Neutered, Domestic Long-haired cat, Tigger a 3 year old, male Neutered, Domestic Short-haired cat, Kitty a 4 year old, female Neutered, Domestic Short-haired cat and Mable, a female neutered, 2 year old, Domestic Short hair cat) of unknown weight were given FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown) administered by the animal's owner, once every 30 days for the last year. On 04 OCT 2019 the owner reported that the cat's still had fleas. The owner was being bitten in the home and there was a home infestation.
04-Oct-2019	UAE; 19UK003357; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	Sep-2019*	N/A	D-D	As reported by the animal owner, a 7 year old male cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown), route and frequency unknown, administered by the cat's owner on an unknown date. The owner reported that since they administered the FRONTLINE PLUS, the cat has been ill, so the owner was taking the cat to the vets. The owner thought it was too much of a coincidence that the cat was bad after using the de-flea product. Date of adverse event added for submission purposes only.

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ED_005739D_00014391-00184

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
04-Oct-2019	UAE; 19UK003361; Hampshire; United Kingdom	**Species:** Canine **Breed:** Retriever (Labrador, Chocolate) **Sex:** F **Sex qualifier:** Unknown **Age:** 10.50 Week(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** AFOXOLANER 18.75 MG / MILBEMYCIN OXIME 3.75 MG CHEWABLE TABLETS; **Route:** unknown **Was the product used ok?:** No (Contraindication per label)	24-Aug-2019	03-Oct-2019	5 Week(s) 5 Day(s)	D-C	As reported by the attending vet, Daisy an intact female Labrador canine aged 10.5 weeks (signalment otherwise unknown) was given NEXGARD SPECTRA (assumed NEXGARD SPECTRA S, batch and expiry unknown) on 17 SEP 2019 orally by the attending vet for routine parasite control. The attending vet reports that the puppy was seen in clinic on 17 SEP 2019 for a second vaccination. It was noted that the puppy had areas of alopecia on her head and around her eyes, with slight skin thickening around her eyes. Demodex mites were suspected but the animal owner declined skin scrapes or further work up. NEXGARD SPECTRA was prescribed for routine parasite control and to cover the possibility of Demodex mites at that time. The chew was given to the puppy with no difficulties. The puppy was seen again by the attending vet on 03 OCT 2019 (16 days following product administration) for a suspected allergic reaction, thought to be unrelated to the previous condition. The puppy had swelling of her head and face with some erythema. At this appointment it was noted that the alopecia and thickened skin was much worse and now affected most of the head as well as the chest, legs and trunk. Skin scrapes were performed and one Demodex mite was found. The swollen head had appeared after being on a walk and was suspected to be due to a different reason. The puppy was treated for this with a one off injection and Piriton and is now much improved. The puppy also received FRONTLINE (assumed FRONTLINE SPOT ON DOG S, batch and expiry unknown) on 24 AUG 2019 (puppy age estimated to be 5.5 weeks at administration). This case is classified as both 'SLEE' and 'Adverse Reaction' but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse Reaction', has been transmitted. UPDATE 04 NOV 2019: Following internal review product problem type SLOE added for NEXGARD SPECTRA. No other changes were made.
05-Oct-2019	UAE; 19UK003370; -; United Kingdom	**Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Jun-2019*	Jun-2019*	from the first month they started using Frontline.	D-D	As reported by the animal owner, a 7 month old, male Labrador canine (signalment otherwise unknown) was given FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) starting 4 months ago (assumed JUN 2019) monthly at an unknown dose by the animal owner for an unknown reason. The animal owner reports that the first month they started using the product (when the dog was 14 weeks old) they noticed red spots on the dog's stomach and he started aggressively scratching. The animal owner put this down to a recent change in food. The animal owner persisted with FRONTLINE and the dog's food and then decided it must be his food so they changed this over 8 weeks ago (estimated AUG 2019). The dog's FRONTLINE dose wasn't delivered last month (assumed SEP 2019) so the dog ended up accidentally skipping a month. During this month, the dog's skin cleared up and he stopped scratching. Last week the animal owner gave the dog his dose of FRONTLINE, food is the same, and the dog's spots and aggravated skin problem have reappeared. The animal owner can now only put this down to FRONTLINE. The dog is very fit and well other than this.
05-Oct-2019	UAE; 19UK003371; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products**	Sep-2019*	2019*	N/A	D-D	As reported by the animal owner, approximately 2 felines (signalment otherwise unknown) were given FRONTLINE SPOT ON CAT (batch and expiry unknown) twice in two months (estimated SEP 2019 and OCT 2019) topically by the animal owner as a parasiticide. The animal owner reports that they've also tried

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ED_005739D_00014391-00185

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					lots of things around the home to keep clean, peppermint oil, cider vinegar and the cats still have fleas. The cats are so upset in themselves. Start date for submission purposes only.
06-Oct-2019	UAE; 19UK003373; -; United Kingdom	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	01-Oct-2019*	0 Day(s)	D-D	As reported by the animal owner, a female Golden Retriever canine aged 12 years (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON DOG L (batch and expiry unknown) on 01 OCT 2019 topically to the back of the neck above the shoulder and directly onto the skin, by the animal owner as a parasiticide. The animal owner reports that they used the product as the dog was scratching and they found a couple of fleas. Six days after product administration the dog was scratching again and the animal owner found she still had fleas, they caught three. The dog is 12 years old and this is the first time she has had fleas.
07-Oct-2019	UAE; 19UK003376; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON; **Route:** unknown **Was the product used ok?:** Unknown to Company	Jun-2019*	2019*	3 Month(s) 2 Week(s)	D-D	As reported by the animal owner, approximately 2 felines (signalment otherwise unknown) were given FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown) by the animal owner in JUN 2019 as a parasiticide (no further information available). The animal owner reports that at this time they also sprayed the house, washed bedding etc and continued to do all that was recommended by ourselves and other agencies. The first pack was the original FRONTLINE 3 pipette, and 4 weeks later (JUL 2019) the animal owner bought the 6 pack which is supposed to kill the eggs (assumed FRONTLINE PLUS SPOT ON CAT, batch and expiry unknown). The cats have now had 3 lots of treatment, two with the new formula (assumed FRONTLINE PLUS) and the animal owner is very disappointed to say that not a day has gone by without watching the cats scratching furiously. On combing, the animal owner finds fresh flea dirt, eggs and adult fleas very much alive. Both the cats are house cats, only going out to the vets when needed. The animal owner lives on the first floor so they don't have access to the outside. The animal owner bought the product through a retailer online so they do not believe they have used a copied product. Start date for submission purposes only.
07-Oct-2019	UAE; 19UK003379; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Others)	N/A	07-Oct-2019*	1 Week(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M) batch number and expiry date unknown, route and frequency unknown, administered by the dog's owner on approximately 30 SEP 2019. The owner reported on 07 OCT 2019 (a week later) that they had spotted a few fleas on the dog in the last few days. The owner did report however that the day the dog was treated in the morning, the owner had to bath the dog because of mud on his cost.
07-Oct-2019	UAE; 19UK003380;	**Species:** Canine **Breed:** Beagle	1	1	0	**Product used:** FIPRONIL SPOT	N/A	07-Oct-2019	2 Day(s)	D-D	As reported by the animal owner, Poppy a female, neutered, Beagle dog, aged 4 years and weighing 16 kg was treated with

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Collection of an AE report does not constitute an admission by BIAH that out product caused or contributed to the AE.
Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014391-00186

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; United Kingdom	**Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 16 kg				ON DOG **Other products used:** Flea home spray; Bob Martin product; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					FRONTLINE SPOT ON DOG M (batch number: S21212AW and expiry date: AUG 2021), applied topically by the dog's owner on 05 OCT 2019 after the owner had seen fleas and after not being happy with a Bob Martin product. On 07 OCT 2019 the owner reported that they wished they had bought FRONTLINE PLUS as it killed the eggs. The dog was also biting her tail. The husband was also being bitten and so the owner thought they was an infestation. The owner would keep on hoovering and using a flea spray to try to get on top of the flea cycle. The owner would also use a flea product every 30 days as had not been previously.
07-Oct-2019	UAE; 19UK003386; -; United Kingdom	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 14.90 Year(s) **Weight:** 19.8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Bravecto tablet; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	N/A	07-Oct-2019	6 Day(s)	D-D	As reported by the animal owner, Winston a male Staffordshire Bull Terrier cross aged 14.9 years and weighing 19.8 kg (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON DOG M (batch number S62720BW expiry date 01 SEP 2021) on 01 OCT 2019 topically to the skin on the back of the neck by the animal owner as a parasiticide. The animal owner reports that they purchased the product from a pharmacy and applied to their dog that day. Today (Monday, 07 OCT 2019) the animal owner has seen fleas on their dog. Their dog still has fleas and they don't feel confident that their cat hasn't so they have made a vet's appointment. The animal owner treats their pets every six months or less, they treat the animals all year round but sometimes they get a Bravecto tablet from the vet. The animal owner started using the product on 01 OCT 2019, they first saw fleas on 07 OCT 2019, and before 01 OCT 2019 they can't remember the last 4 dates they used the product. People in the home are not being bitten by fleas, the pets spend time indoors only, the animal owner is seeing less than 5 fleas at a time, the pets only get bathed or go swimming no more than once a week and this is not within 2 days of the product being applied, the animal owner has not lived in the home for less than a year, the home has been treated with an environmental flea treatment, the pet's bedding has been washed at over 60 degrees and all areas the pets can access are regularly vacuumed. On 08 October 2019 the animal owner reported that the dog does not mix with other dogs, they have a back yard and not a garden.
10-Oct-2019	UAE; 19UK003389; -; United Kingdom	**Species:** Canine **Breed:** Canine Crossbred **Sex:** F **Sex qualifier:** Neutered **Age:** 6.92 Year(s) **Weight:** 15.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	02-Sep-2019	02-Sep-2019	within 6 hours	D-B	6.9 year old 15.5kg female neutered Springer Collie cross breed dog was treated with Frontline Plus Spot-on Dog M on 2 Sept 2019. Within 6 hours, she initially had a seizure. then was scratching a lot and had a temperature. The scratching and pulling hair out lasted for about 2 weeks, until she had lots of bald spots on her back end, legs and face. 2 weeks after the initial treatment we had to give her antihistamines and steroids to minimise the scratching. UPDATE 01 NOV 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot S62720BW, expiry 2021-09-30. Final complaint evaluation: A product quality complaint for FRONTLINE SPOT ON DOGS batch S62720BW was received by BIAH QA on 16th of October 2019. The complaint description is adverse event. This is the first complaint regarding this defect for this batch. The sample complaint is not received and no pictures are attached for this case. Not reviewed : the retention sample is stored for identification purposes. Therefore, it is not applicable to this kind of defect. Batch record investigation. Bulk batch: S627.

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ED_005739D_00014391-00187

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											Manufacturing date: 02/10/2018. Expiry date: N/A. Manufacturing quantity: 2399 liters. No deviation and observation are associated to this batch. This batch was not concerned by any change control. The results of QC testing are conform to specifications. All the parameters verified during the manufacturing of this batch of bulk are conform. Root cause: No root cause could be identified on Toulouse plant. Description: After verification of batch records and certificate of analysis, no relation can be established between this related adverse event and the manufacturing process on Toulouse plant. No impact for the quality of product, for the batch and other batches and no impact for the market. The defect is not linked to any product quality issue. Conclusion: The root cause is external. This defect is categorized as major without impact on the market and is not
08-Oct-2019	UAE; 19UK003392; -; United Kingdom	**Species:** Canine **Breed:** Spaniel (English Cocker) **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 24 kg*	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** Vetmedin pimobendan chewable 5 mg MRP; Diazepam 10 mg rectal; Diazepam IV; Phenobarbital; FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	01-Oct-2019	N/A	D-B	As reported by the attending vet, Molly a neutered female English Cocker Spaniel canine born on 07 FEB 2009 and weighing approximately 24 kg, and in good condition, was given FRONTLINE COMBO (assumed FRONTLINE COMBO SPOT ON DOG M, batch number R60906AR expiry date MAR 2020) on 01 OCT 2019 topically to an unknown site by the animal owner for parasite control. The dog did not lick the application area. The dog had had only normal FRONTLINE before (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown). The attending vet reports that they had not seen the dog in practice since 2016 so there is a substantial gap in history. The attending vet does not know where the FRONTLINE COMBO was purchased as it was not purchased from the reporting vet. An hour after product administration the dog started to show neurological signs. there were tremors initially localised facial twitches. The dog was seen at the reporting vets at 6:30 pm. In house bloods were taken and nothing abnormal was detected. Abdominal and heart scans were performed, nothing abnormal was detected on the abdominal scan, the heart scan showed signs of increased heart size so the dog was started on VETMEDIN 5 MG tablets (assumed VETMEDIN CHEW 5 MG CHEWABLE TABLETS FOR DOGS, batch and expiry unknown). Diazepam 10 mg rectal was used for neurological signs and the dog was also sent home with a further Diazepam 10 mg rectal to give if its seizures started again or increased. The dog was sent home to observe as it was stable and settled. Later that night as the dog's seizures had increased in intensity (head was extended and rigid limbs), the dog was given the Diazepam 10 mg at 8:30 pm. The dog attended the out of hours clinic at 10:20 pm as the seizures had started to increase in intensity, with rigid head extension and rigid limbs. When the dog arrived it was panting but not fitting. Heart rate was normal and nothing abnormal was detected on an abdominal exam. The animal owner declined hospitalisation. On 02
09-Oct-2019	UAE; 19UK003393; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products	N/A	01-Oct-2019*	N/A	D-D	As reported by the animal owner, Alfie a male feline aged 13 years (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) monthly (no further details available). The animal owner reports that they recently had cause to take Alfie to the vets and whilst being examined the vet located fleas on him. The animal owner had only treated Alfie the week before with FRONTLINE PLUS ad have treated him every month. The vet has now advised the animal owner to change from FRONTLINE to another brand, this is due to the fact that the vet

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ED_005739D_00014391-00188

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: unknown **Was the product used ok?:** Unknown to Company					has seen a huge increase in the amount of animals on FRONTLINE that now have fleas, which means that the product is not working. The animal owner has had to de-flea their house. Start date for submission purposes only.
10-Oct-2019	UAE; 19UK003407; -; United Kingdom	**Species:** Canine **Breed:** Spaniel **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 18.8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Aug-2019*	Aug-2019*	N/A	D-D	As reported by the animal owner, Oscar, a 2 year old male neutered Spaniel canine weighing 18.8 kg and in good condition, was administered FRONTLINE PLUS SPOT ON DOG M) (batch and expiry unknown) topically to an unknown site, by the animal owner, at a dose of 1 dose every 30 days, from 2 months ago (AUG 2019) for an unknown indication. The animal owner reports that the animal likes to swim at least three times a week but that they are aware not to let him get wet for 48 hours after application of FRONTLINE PLUS. The animal owner has got all the sprays and is using them regularly and is using a flea comb every day but they are still seeing fleas. The animal owner is not being bitten at home.
11-Oct-2019	UAE; 19UK003419; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	23-Sep-2019*	30-Sep-2019*	approximately 1 Week(s)	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number: S41306AW and expiry date: unknown), 1 pipette applied to the back of the cat's neck, administered by the cat's owner on approximately 23 SEP 2019. The owner reported that one week later (date estimated as 30 SEP 2019) they noticed a huge bald patch and hair loss on the back of the cat's neck where they had administered the product. The owner felt terrible that this had happened to the cat. This was the first time they had used FRONTLINE PLUS in many years. The owner had 3 cats at their work and George was one of them. The cat had never reacted to any flea treatment's used previously. The cat was normally treated with Bob Martin flea treatment 4 kg and had also previously been treated with advantage in the past. The owner was not going to take the cat to the vet as there was no red or sore skin reaction, just hair loss.
11-Oct-2019	UAE; 19UK003420; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a female canine (signalment otherwise unknown) was administered FRONTLINE SPOT ON DOG S (batch T20305PL expiry DEC 2021) (details unknown) by the animal owner for an unknown indication. The animal owner reports that they have used the product but it appears not to be working. After 2/3 weeks the fleas were not knocked down, which they thought was odd. The dog did not have a vast amount but as part of diligence they wanted to treat her. A second treatment was given but with no effect. It was only because the animal owner went to their local regular vet and they informed them that they had received other complaints regarding FRONTLINE not working. There was no upselling or biased opinion to the company. The animal owner's friend 12 miles away also treated their dog at the same time as the animal owner, with the same treatment, purchased from the same place and has had the same problem. She had to get a medicated flea treatment. The animal owner's vet commented that it may be a faulty batch. Start date added for submission purposes only. UPDATE: 02 DEC 2019: QA results received. Investigation completed for FIPRONIL SPOT ON DOG Lot T20305PL, expiry. Final complaint evaluation BIAH QA received a product quality complaint for FRONTLINE Spot on Dog, batch T20305PL, on the

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ED_005739D_00014391-00189

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											18th of October 2019. The complaint description is lack of efficacy. This is the first complaint regarding this defect for this batch. Not reviewed : the retention sample is stored for identification purposes. Therefore, it is not applicable to this kind of defect. The complaint sample is not received. No pictures are attached for this case. Batch record investigation: Bulk batch T203 :Manufacturing date: 28/01/19. Expiry date: N/A Manufacturing quantity: 1199.2 liters. No deviation and observation are associated to this batch. This batch was not concerned by any change control. The results of QC testing are conform to specifications. All the parameters verified
11-Oct-2019	UAE; 19UK003424; Dorset; United Kingdom	**Species:** Canine **Breed:** Collie **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 19 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Yes	N/A	2019*	N/A	D-D	As reported by the animal owner via a distributor, Isle, a 1 year old female Collie canine, weighing 19 kg and in unknown condition, was administered FRONTLINE PLUS SPOT ON DOG M (batch S62703AW expiry SEP 2021) (details unknown) at a dose of one pipette monthly, by the animal owner for flea prevention. The animal owner reported that they are using FRONTLINE PLUS and it that it doesn't work. They spoke to a vet who advised that the product doesn't work and not to use it. Start date added for submission purposes only.
11-Oct-2019	UAE; 19UK003427; -; United Kingdom	**Species:** Canine **Breed:** Beagle **Sex:** X **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 14 - 19 kg	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Environmental Flea treatment; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	Sep-2019*	0 Day(s)	D-D	As reported by the animal owner, four canines (signalment otherwise unknown) were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M) (batch and expiry unknown) (details unknown) by the animal owner in SEP 2019 for an unknown indication. The animal owner reports that they used the six pack of FRONTLINE PLUS on their four dogs at the beginning of SEP 2019. The FRONTLINE PLUS has not worked and all the dogs still have fleas. They contacted their vet and had to get a different treatment. UPDATE 22 OCT 2019: The owner reported that the 4 Beagle dogs (Stanley a male, 4 year old weighing 19 kg, Tilly a female, 10 year old dog weighing 14 kg, Misty a female, 5 year old dog, weighing 14 kg and Spike a female, 10 year old dog, weighing 14 kg), all were treated with FRONTLINE PLUS SPOT ON DOGS M (as per instructions on the pack). The last 4 dates of application were JAN 2019, MAR 2019, AUG 2019 and mid SEP 2019. The owner used the product all the year round, but only when the fleas were seen. The people in the house were being bitten by the fleas and many fleas were being seen, 5 or more at the same time. The owner reported that the dogs spent most of their time indoors. The animal's were never bathed and never went swimming. The owners had treated the home with environmental flea treatment, had washed the pet's bedding at over 60°C and had vacuumed all areas the pets could access. The owner had lived in their home for more than 1 year. Case linked to 19UK003550. UPDATE 23 OCT 2019: The animal owner reported that they are not experiencing any sort of infestation. They went to the vet at the beginning of October and got some drops from them and the dogs and cat (see linked case) are now free from fleas.
11-Oct-2019	UAE; 19UK003428; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	N/A	07-Oct-2019*	0 Day(s)	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M) (batch and expiry unknown) (details unknown) by the animal owner on approximately

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ED_005739D_00014391-00190

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					07 OCT 2019 to remove an outbreak of fleas. The animal owner reports that four days later they are still finding live fleas on their dog, even around the area where the medicine was placed. The animal has a really thick coat.
13-Oct-2019	UAE; 19UK003436; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	10-Oct-2019*	1 Week(s)	D-D	As reported by the attending vet, a feline (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) on 03 OCT 2019 by the animal owner (no further information available). The animal owner reports that they still found one flea and some eggs today in the flea comb. The house has been treated meticulously from top to bottom, with cleaning, vacuuming and spray, as has the car and cat bedding. Start date added for submission purposes only.
14-Oct-2019	UAE; 19UK003443; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 5.4 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL SPOT ON CAT; FIPRONIL SPRAY; Advocate; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	Jul-2019*	N/A	D-D	As reported by the animal owner, Simba, an 8 year old male feline weighing 5.4 kg (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch S41504 expiry NOV 2021, further details unknown), FRONTLINE SPOT ON CAT (batch R21801 expiry NOV 2020) and FRONTLINE SPRAY (batch and expiry unknown) topically to the back of the neck, by the animal owner for an unknown indication. It is unclear if all the products were used at the same time or separately. The owner also reported that the cat received Advocate , which is injected every three months (no further details were provided). The animal owner reports that they have used the products before but that this time it didn't work and their cat still has fleas quite badly. The animal owner reports that they use FRONTLINE throughout the summer and that they have always used it from May to September. They started using the products in about MAY 2019 for their current flea issue and first noticed fleas on the animal in about JUL 2019 in the hot weather. The last four dates that the products were applied were approximately 15 MAY 2019, 15 JUN 2019, 15 JUL 2019 and 15 AUG 2019. the animal owner applies the product under the collar on the back of the neck and no one in the home is being bitten. The animal spends time indoors and outdoors. The animal owner is seeing many fleas - more than 5 at the same time and flea eggs, the animal never bathes or goes swimming and the animal owner has treated the home with an environmental flea treatment and regularly vacuumed all areas that the pet can access. UPDATE 02 DEC 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot S41504, expiry 2021-11-30. Final complaint evaluation A product quality complaint for FRONTLINE PLUS SPOT ON CATS, batch number S41504 was received by BIAH QA on the 23th of October 2019. The complaint description is: LOE. This is the first complaint regarding this kind of defect for this batch. The complaint

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ED_005739D_00014391-00191

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
14-Oct-2019	UAE; 19UK003449; -; United Kingdom	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 39.5 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	2013*	23-Sep-2019*	0 Day(s)	D-C	As reported by the animal owner, Buster, a 9 year old male neutered German Shepherd Dog canine, weighing 39.5 kg and in good condition, was administered FRONTLINE SPOT ON DOG L (batch S20921RX expiry JUN 2020) topically to an unknown site, by the animal owner from 6 years ago (2013) for preventative care. Three weeks ago (estimated 23 SEP 2019) the animal owner applied the product purchased online that they have always used to purchase from. This recent batch was purchased in JUL 2019. At the point of application the animal held the head in an odd position. At first the animal owner thought that maybe he had an ear infection. The animal was carrying himself on and off almost like he had lost his balance - kind of like having some sort of fit. Approximately a week after application the animal owner noticed lumps, possibly scabs, at the application site. This was cleaned with Hibiscrub that they had at home and they have been cleaning it every day. It looks ok. The animal owner took the animal to the vets on either 08 or 09 OCT 2019 to be checked because of the way that he was holding himself. The vet said not to use the FRONTLINE anymore because he looks to have had a reaction. No treatment was given.
14-Oct-2019	UAE; 19UK003452; -; United Kingdom	**Species:** Feline **Breed:** Feline crossbred **Sex:** F **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 4.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Aug-2019*	Aug-2019*	N/A	D-D	As reported by the animal owner, Squeeker, a 14 year old female neutered Moggie feline, weighing 4.5 kg and in good condition, was administered FRONTLINE PLUS SPOT ON CAT (batch S41303AW expiry OCT 2021, further details unknown) by the animal owner, from three months ago (AUG 2019) for an unknown indication. The animal owner is still seeing fleas and the animal has rough blood spots on the body and is itching lots. The animal owner is taking the animal to the vets in the next few days. The animal owner is not being bitten in the home.
16-Oct-2019	UAE; 19UK003454; -; United Kingdom	**Species:** Canine **Breed:** Pomeranian **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Week(s) **Weight:** 0.48 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** Nobivac DHP; Nobivac L4 Suspension for Injection for Dogs; Panacur Small Animal 10% Oral Suspension; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Sep-2019	25-Sep-2019	N/A	D-B	Serious Suspected Adverse Reaction. Case reports a 10 week old female entire Pomeranian. No previous illness or disease. She had been hand reared from birth. On 25 September 2019 the dog was vaccinated with Nobivac DHP and L4. The dog was also treated with Panacur liquid and frontline spray. The owner reported the needle broke when the dog was injected, and the dog cried out. She continued to cry all evening. On 26 September 2019 5am the dog was struggling to get up, and the legs were spasming. The dog continued to cry, and was lethargic and urinated in the bed. She seemed ataxic on presentation to the practice. On clinical exam her respiratory rate was 36 bpm, heart rate 168 bpm, temperature 38.3 degrees Celsius. Otherwise normal. Vet reports the needle hub came off the syringe during vaccination , it did not break. No further information expected.
15-Oct-2019	UAE; 19UK003455; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown)	1	1	0	**Product used:** FIPRONIL SPOT ON DOG	25-Sep-2019*	01-Oct-2019*	N/A	D-D	As reported by the animal owner, a male canine (signalment otherwise unknown) was given FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) twice in 10 days (first treatment was 3 weeks ago, estimated 25 SEP

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ED_005739D_00014391-00192

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					2019) given by the animal owner as a parasiticide. The animal owner reports that they used two pipettes in 3 weeks under their vet's guidance. They have also treated their home. Sadly the dog still has fleas very much alive running through his coat. The dog has had two treatments within 10 days. It would appear that the FRONTLINE has not the efficacy it used to have. An expensive failure and continued discomfort for their dog. Start date for submission purposes only.
15-Oct-2019	UAE; 19UK003456; -; United Kingdom	**Species:** Canine **Breed:** Greyhound **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** unknown **Was the product used ok?:** No (Treatment / vaccination program not respected)	N/A	14-Oct-2019	0 Day(s)	D-D	As reported by the animal owner, a female Greyhound canine (signalment otherwise unknown) was given FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) via an unknown route by the animal owner for parasite control. The animal owner reports that they found lots of fleas on their Greyhound yesterday (14 OCT 2019). The dog had her last FRONTLINE treatment on 01 SEP 2019. They are not sure if it was FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown) as the animal owner did not realise they were different products until today. They applied FRONTLINE to the dog yesterday (14 OCT 2019) tea time and this evening (15 OCT 2019) she is still covered in fleas. The animal owner is not sure if to a lesser extent or not. They are going away for three weeks and the dog is going to be staying with a friend, obviously they need to get rid of her fleas before then. The animal owner has washed all the dog's bedding etc, she has never had a break in her treatment for fleas before.
15-Oct-2019	UAE; 19UK003464; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	15-Oct-2019	N/A	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M) (batch and expiry unknown) (details unknown) on 26 SEP 2019 for fleas. The animal owner reports that they spotted a few fleas on their dog and they applied spot on 26 SEP 2019. Today (15 OCT 2019) they have seen more fleas and the animal is scratching a lot.
15-Oct-2019	UAE; 19UK003474; -; United Kingdom	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 3.400 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	17-Sep-2019	18-Sep-2019	1 Day(s)	D-C	As reported by the animal owner, Ozzy, an 11 year old female neutered Domestic Longhair feline, weighing 3.4 kg and in good condition, was administered FRONTLINE PLUS SPOT ON CAT (batch S41303AW expiry OCT 2021) topically to an unknown site, by the animal owner, at a dose of 1 pipette, 4 weeks ago (17 SEP 2019) as another owner whose cat has fleas had been in contact with the animal. The animal is an indoor cat, and has a history of cystitis and so is on an urinary diet. The next day after application the animal started running around crying and being sick. Fur started coming out and the animal has lost weight, now weighing 3 kg. The animal has been to the vets and has been given a steroid injection. On 17 OCT 2019 the attending vet reported that they examined the cat on 20 SEP 2019 and found that the cat was over grooming and vomiting due to fur balls. The animal owner had reported that the cat seemed withdrawn but with a normal appetite. The animal owner did not report any other strange behaviours such as "running around crying" the cat appeared to be in a stable condition in the consult. Temperature was unremarkable. The vet considered the cat to have a typical Flea Allergic Dermatitis presentation. The cat was given an injection of steroid to help

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ED_005739D_00014391-00193

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											control pruritus. Haematology and biochemistry analysis was unremarkable. Indorex was provided to the owner to treat a home flea infestation. On 15 OCT 2019 the attending vet examined the cat again. Fleas were still present on the cat, it was given a repeat injection of steroid for FAD and pruritus. The cat was also given Prinovox to replace FRONTLINE. This case is classified as both 'SLEE' and 'Adverse Reaction' but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse Reaction', has been transmitted.
07-Oct-2019	UAE; 19UK003476; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	May-2019*	01-Oct-2019	N/A	D-D	As reported by the animal owner, approximately 2 felines (signalment otherwise unknown) were given FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) by the animal owner from MAY 2019 (no further details available). The animal owner reports that they signed up to a subscription of FRONTLINE PLUS to have it delivered into their house. They are now into 5 months of usage and the animal owner says that to be honest they have never seen anything like it. Their cats are constantly scratching, they have flea eggs literally falling off their cats as well as flea poo . They feel like their house is infested now as our product isn't working and now they have a problem. The animal owner is hoovering twice a day, they've treated the house on a few occasions and feel now their house may need fumigating. Start date for submission purposes only.
16-Oct-2019	UAE; 19UK003478; -; United Kingdom	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 27 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Flea spray; Flea bomb; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	Mar-2019*	02-Oct-2019	19 Day(s)	D-D	As reported by the animal owner, Molly a female Golden Retriever canine aged 7 years and weighing 27 kg (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON DOG L (batch and expiry unknown) for several months (starting in MAR 2019) topically between the shoulder blades every month by the animal owner for parasite control. The animal owner reports that they have been buying FRONTLINE PLUS on a monthly subscription from a local pet shop for their 3 dogs (see linked cases 19UK003479 and 19UK003481) for several months. Their house is vacuumed regularly, the dogs are brushed and cleaned and shampooed regularly, bedding is washed etc., they have spent a lot of money on the product and it is not working. It has got so bad now with their poor dogs itching and pulling their hair out that they have to take them to the vet. The animal owner states that this should not be happening, the product is not doing what we say it will or what it should be doing. The animal owner feels this is totally cruel to the animals because they are now suffering. The animal owner has also used a flea spray (product unknown) and flea bomb. The animal owner first noticed fleas on their pets 2 weeks ago (estimated 02 OCT 2019), and the last four dates the products were applied were 11 OCT 2019, 13 SEP 2019, 10 AUG 2019 and 12 JUL 2019. The animal owner applied the product as instructed between the shoulders on parted fur, direct to the skin. People in the home are not being bitten by fleas, the animals spend time indoors and outdoors, all animals in the home have been treated, the animal owner is seeing occasional fleas, the pets do not get bathed or go swimming more than once a week and this does not occur within 2 days of product application, the animal owner has not lived in the home for less than a year, the home has been treated with an environmental flea treatment, the pet's bedding has been washed at over 60 degrees and all areas the pets can access are regularly vacuumed. The

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ED_005739D_00014391-00194

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
16-Oct-2019	UAE; 19UK003479; -; United Kingdom	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 12 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Flea spray; Flea bomb; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	Mar-2019*	02-Oct-2019	19 Day(s)	D-D	As reported by the animal owner, Nina a female Pug cross Pomeranian canine aged 7 years and weighing 12 kg (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON DOG M (batch and expiry unknown) for several months (starting in MAR 2019) topically between the shoulder blades every month by the animal owner for parasite control. The animal owner reports that they have been buying FRONTLINE PLUS on a monthly subscription from a local pet shop for their 3 dogs (see linked cases 19UK003478 and 19UK003481) for several months. Their house is vacuumed regularly, the dogs are brushed and cleaned and shampooed regularly, bedding is washed etc., they have spent a lot of money on the product and it is not working. It has got so bad now with their poor dogs itching and pulling their hair out that they have to take them to the vet. The animal owner states that this should not be happening, the product is not doing what we say it will or what it should be doing. The animal owner feels this is totally cruel to the animals because they are now suffering. The animal owner has also used a flea spray (product unknown) and flea bomb. The animal owner first noticed fleas on their pets 2 weeks ago (estimated 02 OCT 2019), and the last four dates the products were applied were 11 OCT 2019, 13 SEP 2019, 10 AUG 2019 and 12 JUL 2019. The animal owner applied the product as instructed between the shoulders on parted fur, direct to the skin. People in the home are not being bitten by fleas, the animals spend time indoors and outdoors, all animals in the home have been treated, the animal owner is seeing occasional fleas, the pets do not get bathed or go swimming more than once a week and this does not occur within 2 days of product application, the animal owner has not lived in the home for less than a year, the home has been treated with an environmental flea treatment, the pet's bedding has been washed at over 60 degrees and all areas the pets can access are regularly vacuumed. The
16-Oct-2019	UAE; 19UK003481; -; United Kingdom	**Species:** Canine **Breed:** Pomeranian **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Flea spray; Flea bomb; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	Mar-2019*	02-Oct-2019	19 Day(s)	D-D	As reported by the animal owner, Lilly a female Pomeranian canine aged 7 years and weighing 5 kg (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON DOG S (batch and expiry unknown) for several months (starting in MAR 2019) topically between the shoulder blades every month by the animal owner for parasite control. The animal owner reports that they have been buying FRONTLINE PLUS on a monthly subscription from a local pet shop for their 3 dogs (see linked cases 19UK003479 and 19UK003478) for several months. Their house is vacuumed regularly, the dogs are brushed and cleaned and shampooed regularly, bedding is washed etc., they have spent a lot of money on the product and it is not working. It has got so bad now with their poor dogs itching and pulling their hair out that they have to take them to the vet. The animal owner states that this should not be happening, the product is not doing what we say it will or what it should be doing. The animal owner feels this is totally cruel to the animals because they are now suffering. The animal owner has also used a flea spray (product unknown) and flea bomb. The animal owner first noticed fleas on their pets 2 weeks ago (estimated 02 OCT 2019), and the last four dates the products were applied were 11 OCT 2019, 13 SEP 2019, 10 AUG 2019 and 12 JUL 2019. The animal owner applied the product as instructed between the shoulders on parted fur, direct to the skin. People in the home are not being bitten by fleas, the animals spend time indoors and outdoors, all animals in the home have been treated,

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ED_005739D_00014391-00195

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											the animal owner is seeing occasional fleas, the pets do not get bathed or go swimming more than once a week and this does not occur within 2 days of product application, the animal owner has not lived in the home for less than a year, the home has been treated with an environmental flea treatment, the pet's bedding has been washed at over 60 degrees and all areas the pets can access are regularly vacuumed. The animal
16-Oct-2019	UAE; 19UK003484; -; United Kingdom	**Species:** Canine **Breed:** Cockapoo **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	09-Oct-2019	0 Day(s)	D-D	As reported by the animal owner, a female Cockapoo canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M) (batch and expiry unknown) (details unknown) by the animal owner on 09 OCT 2019 for an unknown indication. The animal owner reports that they treated their animal with FRONTLINE, although they hadn't seen any fleas, but since treatment a week ago they now see fleas on her.
16-Oct-2019	UAE; 19UK003485; -; United Kingdom	**Species:** Canine **Breed:** Spaniel (Cocker) **Sex:** M **Sex qualifier:** Mixed **Age:** 4.00 Year(s) **Weight:** 15 - 17 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Yes	N/A	2019*	N/A	D-D	As reported by the animal owner, Brock, a 14 year old neutered weighing 17 kg, and Traddock, a 4 year old entire weighing 15 kg, both male Cocker Spaniel canines in good condition, were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M) (batch and expiry unknown) by the animal owner every 30 days all year round for an unknown indication. The animal owner is still seeing fleas. The animals were treated in the last week and so the animal owner will wait the three weeks before application. They are not being bitten at home. Start date added for submission purposes only.
17-Oct-2019	UAE; 19UK003493; -; United Kingdom	**Species:** Canine **Breed:** Schnauzer (Miniature) **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	14-Oct-2019	17-Oct-2019	3 Day(s)	D-D	As reported by the animal owner, Minnie a neutered female miniature Schnauzer canine aged 7 years and in good condition (signalment otherwise unknown) was given FRONTLINE (assumed FRONTLINE SPOT ON DOG S, batch and expiry unknown) topically to an unknown site by the animal owner as a parasiticide. The animal owner reports that they are still seeing fleas. The animal owner asked if they can shampoo the dog when FRONTLINE was applied 3 days ago. The animal owner is not being bitten in the home. They are also using spray to try and kill the eggs. UPDATE 28 OCT 2019: Following internal review the tick box for "was product used correctly" was ticked unknown. No other changes were made.
17-Oct-2019	UAE; 19UK003496; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown	N/A	17-Oct-2019	N/A	D-D	As reported by the animal owner, a male feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) (details unknown) by the animal owner, at a dose of 1 dose monthly for an unknown indication. The animal owner reports that they last applied it on Monday 14 OCT 2019 and tonight, 17 OCT 2019, the animal has come in with two ticks attached to him.

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ED_005739D_00014391-00196

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					
17-Oct-2019	UAE; 19UK003497; -; United Kingdom	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 8.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	N/A	2019*	N/A	D-D	As reported by the animal owner, Mitzie, a 9 year old female neutered Shih Tzu canine, weighing 8.5 kg and in good condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG S) (batch and expiry unknown) topically to an unknown site, by the animal owner, at a dose of 1 dose once monthly, for an unknown indication. The animal owner receives the product on a subscription service. They are still seeing fleas 15 days after the last application. They are not being bitten in the home and will be trying a flea shampoo in the next day or so. Start date added for submission purposes only.
17-Oct-2019	UAE; 19UK003498; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	17-Oct-2019	1 Week(s)	D-D	As reported by the animal owner, approximately two canines (signalment otherwise unknown) were given FRONTLINE advanced (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown) on 10 OCT 2019 (no further information available). The animal owner reports that they treated their pets 1 week ago and they still have fleas.
17-Oct-2019	UAE; 19UK003499; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	2014*	Sep-2019*	0 Day(s)	D-D	As reported by the animal owner, Ben a feline aged 12 years (signalment otherwise unknown) was given FRONTLINE COMBO SPOT ON CAT (batch number R40309CW expiry date JAN 2020) topically to an unknown site at a dose of 1 pipette given by the animal owner monthly for parasite control. The animal owner reports that they have been getting FRONTLINE COMBO from their vet for a number of years, they have never had a problem but they felt that recently it has stopped working for her cat, over the last 2 applications (estimated starting SEP 2019). The cat is completely infested. The animal owner reports that they have been using the product correctly each month for years with no gaps but now has a home infestation and is being bitten. The owner has also washed the cat thinking this would help with the fleas. UPDATE 06 DEC 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot R40309CW, expiry 2020-01-31. Final complaint evaluation: A product quality complaint for FRONTLINE PLUS SPOT ON CATS, batch number R40309CW was received by BIAH QA on the 23th of October 2019. The complaint description is: LOE. This is the first complaint regarding this kind of defect for this batch. The complaint sample is not received and pictures are not attached to this case. Not reviewed : the retention sample is stored for identification purposes. Therefore, it is not applicable to this kind of defect. Batch record review: S403. Manufacturing date: 20/02/2017. Expiry date: NA. Manufacturing quantity: 999 liters. Associated deviation(s): No deviation associated to this batch Change control associated: This batch was not concerned by any change control. Observation(s): No observation associated to this batch. Results of

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ED_005739D_00014391-00197

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											QC testing: Conform at specifications. All parameters verified during manufacturing of this batch of bulk are conform. Batch record review: S40309. Manufacturing date: 28/02/2017. Expiry date: 01/2020. Manufacturing quantity: 260 420
18-Oct-2019	UAE; 19UK003506; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	2011*	2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT) (batch and expiry unknown) (details unknown) by the animal owner for 8 years (from 2011) for an unknown indication. The animal owner reports that they have been using FRONTLINE for over 8 years now for their cat but now more than ever, they are still seeing flea dirt on their cat and some fleas in the house. The animal owner's understanding is that when a flea bites a FRONTLINE treated cat then and only then the flea dies, when it has ingested the FRONTLINE from biting. If this is true then it would explain why flea dirt is still on their cat, fleas maybe jumping on the animal and not biting for a while. Start date added for submission purposes only.
18-Oct-2019	UAE; 19UK003512; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2018*	18-Oct-2019	N/A	D-D	As reported by the animal owner, their 3 cats (signalment otherwise unknown) were treated with FRONTLINE (assumed to be FRONTLINE SPOT ON CAT) batch number and expiry date unknown, route unknown, administered by the cat's owner every month for almost a year as the owner had a monthly subscription. On 18 OCT 2019 the owner reported that the cats still had fleas, the FRONTLINE was not working. The owner hoovered regularly and also de flea'd the cats with a comb and did everything they could as well as using the flea treatment. UPDATE 01 NOV 2019: The animal owner reports that they are getting flea bites and that they have been using the treatment monthly for a year, since they became outdoor cats. The animal owner combs up to 15 fleas off each cat even only a week after treatment, and reports that they have given it the benefit of the doubt more than once and continued to use the treatment in the hope that it would get better and they realised that it isn't going to.
19-Oct-2019	UAE; 19UK003514; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Overdose)	N/A	2019*	N/A	D-D	As reported by the animal owner, a female canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG S, batch and expiry unknown, details unknown) by the animal owner at a dose of 2 doses, for an unknown indication. The animal owner reports that they purchased FRONTLINE for their pets a few weeks ago and they have already used two on their small dog and she is absolutely covered in fleas. They are so disappointed in the product. Start date added for submission purposes only.
20-Oct-2019	UAE; 19UK003517; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used**	N/A	2019*	N/A	D-D	As reported by the animal owner, a female canine (signalment otherwise unknown) was administered FRONTLINE PLUS 10 KG (assumed FRONTLINE PLUS SPOT ON DOG S, batch and expiry unknown, details unknown) by the animal owner, at a dose of 2 doses, for an unknown indication. The animal owner reports that they have given their dog two doses of FRONTLINE PLUS. The first didn't work at all and so they gave her a second dose 5 days later. This also, 36 hours later has not worked. The animal owner asks if they should give a third dose or is the product totally useless and they have wasted money. Start date added for submission purposes only.

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ED_005739D_00014391-00198

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: No (Treatment / vaccination program not respected)					
21-Oct-2019	UAE; 19UK003525; -; United Kingdom	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Pregnant **Age:** 4.50 Year(s) **Weight:** 35 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	N/A	2019*	N/A	D-D	As reported by the animal owner, Annie, a female intact pregnant 4.5 year old Golden Retriever canine weighing 35 kg and in good condition, was administered FRONTLINE SPOT ON (assumed FRONTLINE SPOT ON DOG L, batch and expiry unknown) topically, by the animal owner at an unknown dose every 30 days for an unknown indication. The animal is actually the reporter's daughter's dog and the reporter has brought the animal to their house so that the owner can clean the house. The animal owner asks if it is normal to see fleas after treatment. The animal is pregnant and due to have puppies in 5 weeks. No one is being bitten in either home. Start date added for submission purposes only.
21-Oct-2019	UAE; 19UK003528; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately two felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) by the animal owner for an unknown indication. The animal owner reports that they use the product regularly but their indoor cats fleas have got worse. They are very disappointed. Start date added for submission purposes only.
21-Oct-2019	UAE; 19UK003529; -; United Kingdom	**Species:** Feline **Breed:** Feline various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 3.175 - 6.350 kg*	7	7	0	**Product used:** FIPRONIL SPRAY **Other products used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON; Fogger; Strike back flea spray, fogger, powder; Brewer's Yeast; FIPRONIL SPOT ON CAT; Demetrius Earth Food Grade; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	Jul-2019*	N/A	D-D	As reported by the animal owner, 7 felines, Snax aged 18 years and weighing approximately 3.175 kg, Thunder aged 7 years and weighing approximately 5.897 kg, Storm aged 6 years and weighing approximately 3.175 kg, Sunny aged 5.5 years and weighing approximately 5.897 kg, Jasper aged 5 years and weighing 6.35 kg, Maisie aged 3.5 years and weighing 3.175 kg and Houdini aged 2 years and weighing 5.897 kg (signalment otherwise unknown) were administered FRONTLINE SPRAY (batch and expiry unknown) topically by the animal owner as a parasiticide. The animal owner reports that sadly this was ineffective and so they purchased FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON CAT, batch number S41504AW expiry date NOV 2021) pipettes. It has been nearly a week and the cats are still scratching and they are still pulling out fleas from the flea comb. The animal owner asks how many treatments they are supposed to buy before it actually kills the fleas as they were under the impression they would be dead within a matter of days. The animal owner has spent a fortune and feels that it's getting worse rather than better. They are treating the house regularly too - they have had foggers, powder and sprays as well as vacuuming and washing everything that the cats touch, yet the cats seem to still be covered in these vile insects. The animal owner is not getting what is promised on the box, and they have read that there is an epidemic this year but surely the products should do what they say regardless of an epidemic. It is unfair to the consumer if it is ineffective. On 27 OCT 2019 the animal owner reported that the cats were last treated with FRONTLINE PLUS on 18 OCT 2019, prior to that they used other products and two treatments of

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* indicates Approximate date or weight.

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ED_005739D_00014391-00199

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											FRONTLINE SPRAY a month prior to using FRONTLINE PLUS. The cats are treated when fleas are seen and the cats are indoor cats with a yard for use. The animal owner noticed fleas in JUL 2019 and have used various treatments since including house flea sprays
21-Oct-2019	UAE; 19UK003530; -; United Kingdom	**Species:** Canine **Breed:** Canine various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 39.916 - 45.000 kg*	3	3	0	**Product used:** FIPRONIL SPRAY **Other products used:** FIPRONIL SPOT ON DOG; Vet flea treatment chewable tablet; Fogger; Strike back flea spray, fogger, powder; Brewer's Yeast; Pest Expert Formula C; Demetrius Earth Food Grade; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	Jul-2019*	N/A	D-D	As reported by the animal owner, Ben a Labrador cross canine, Pepper a Golden Retriever canine aged 10 years and both weighing approximately 39.916 kg (88 lbs), and Benson a German Shepherd canine aged 2 years and weighing approximately 45 kg (signalment otherwise unknown) were administered FRONTLINE SPRAY (batch and expiry unknown) (details unknown) topically by the animal owner as a parasiticide. The reporter is the animal owner of Ben but Pepper and Benson are dogs that visit the reporter's home. The animal owner reports that Ben was being treated with a vet treatment (a chewable tablet) every three months , a treatment was late in JUN 2019 and the animal owner retreated him in JUL 2019. All the dogs are taken for walks on the beach and local Gare. The visiting dogs are treated if they have fleas. The animal owner noticed fleas in JUL 2019 and they have used various treatments since including house flea sprays and natural products such as Brewer's Yeast. The dogs were treated with FRONTLINE EXTRA LARGE DOG (estimated FRONTLINE SPOT ON DOG XL, batch and expiry unknown) on 18 OCT 2019. Prior to that the animal owner used FRONTLINE SPRAY and before that they used various other flea treatments. The spray was applied all over the body. The animal owner has just started to get bites again on their arms and torso. Some fleas are dying and others are still lively, still lots of flea dirt. The animal owner has used foggers and strike back flea spray, fogger and powder. The animal owner vacuums regularly, they have washed all the animals' bedding and other household bedding etc. at 60 degrees several times. The dogs swim in the sea but did not swim a few days after treatment. On 28 OCT 2019 the animal owner reported that they found a flea larvae in their bed last night. On 29 OCT 2019 the animal owner reported that FRONTLINE SPOT ON was ordered on 25 JUL 2019 and used in AUG 2019. In AUG 2019 the animal owner's mother's dogs were treated with Beaphar Fiprotec for
22-Oct-2019	UAE; 19UK003539; -; United Kingdom	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	22-Oct-2019*	4 Day(s)	D-D	As reported by the animal owner, two Yorkshire Terrier canines (signalment otherwise unknown) were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG, batch and expiry unknown, details unknown) on 18 OCT 2019 for an unknown indication. The animal owner reports that they bought the product on Friday for both their Yorkshire Terriers and it was applied the same day. Now both the dogs are full of fleas and scratching badly. The animal owner will be canceling their delivery as their dogs have never been so bad.
22-Oct-2019	UAE; 19UK003540; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	N/A	22-Oct-2019*	1 Week(s)	D-C	As reported by the animal owner, a female canine (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown, details unknown) on 15 OCT 2019 for an unknown indication. The animal owner bought the product, got home and put it on their dog, and are now at the vets due to the animal's skin

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ED_005739D_00014391-00200

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - **Weight:** Unknown				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					being red raw, infected, green and smelling pus, hair loss and wounds. The animal has been shaved all over the neck and is on antibiotics and Hibiscrub, and also spray to dry the area out and pain relief. The animal owner wanted to highlight this problem as their poor animal is in such a mess and they have had to pay vets bills, and the vets have confirmed that it was due to the product.
22-Oct-2019	UAE; 19UK003550; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 10.000 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Environmental Flea treatment; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	Sep-2019*	0 Day(s)	D-D	As reported by the animal owner, Brambles a 15 year old, cat, weighing 10 kg and of unknown health status, was treated with FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown) dose unknown applied as per instructions on the pack. The last 4 dates of application were JAN 2019, MAR 2019, AUG 2019 and mid SEP 2019. The owner used the product all the year round, but only when the fleas were seen. The people in the house were being bitten by the fleas and many fleas were being seen, 5 or more at the same time. The owner reported that the animal spent most of their time indoors. The animal was never bathed and never went swimming. The owners had treated the home with environmental flea treatment, had washed the pet's bedding at over 60°C and had vacuumed all areas the pets could access. The owner had lived in their home for more than 1 year. This case is linked to case 19UK003427. The animal owner reported that they are not experiencing any sort of infestation. They went to the vet sat the beginning of October and got some drops from them and the dogs (see linked case) and cat are now free from fleas.
23-Oct-2019	UAE; 19UK003552; -; United Kingdom	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** - **Age:** 11.33 Year(s) **Weight:** 6 kg	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	09-Aug-2019	01-Oct-2019	1 day	D-C	Frontline Plus Spot-on applied to 2 cats, 2 pipettes given one month apart. 24 hours after second application, one cat reacted. Fur has fallen out in the area where product news administered. Skin underneath is bleeding and scabbed. Reaction duration 7 days. Previously exposed but not reacted.
23-Oct-2019	UAE; 19UK003555; Devon; United Kingdom	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 5.000 kg*	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Aug-2017*	Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, 2 felines, Oscar aged 9 years and Marley aged 7 years, both male neutered Domestic Shorthair cats weighing approximately 5 kg, and in good condition, were given FRONTLINE SPOT ON CAT (batch number S20416AW expiry date FEB 2021) from AUG 2017 every 5 weeks topically to an unknown site by the animal owner as a parasiticide. The animal owner reported that the product isn't working anymore because they are seeing fleas and being bitten. This started a few weeks ago (estimated AUG 2019). Marley has a heart condition and has 2 tablets a day for this (product unknown; assumed pre-exhibiting). Oscar reacted to the fleas, the animal owner took him to the vets as a result. He was given an injection of some kind but had no other treatment.
23-Oct-2019	UAE;	**Species:** Canine	1	1	0	**Product used:**	Jul-2019*	Jul-2019	N/A	D-D	As reported by the animal owner, Paddy, a 13 year old male intact

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ED_005739D_00014391-00201

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19UK003558; -; United Kingdom	**Breed:** Spaniel (English Springer) **Sex:** M **Sex qualifier:** - **Age:** 13.00 Year(s) **Weight:** 12 - 13 kg				FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					Springer Spaniel canine, weighing 12 to 13 kg and in good condition, was administered FRONTLINE SPOT ON DOG M (batch S20221AL expiry JAN 2021) topically to an unknown site, by the animal owner, from 3 months ago (estimated to start JUL 2019), at a dose of 1 dose every 4 weeks as part of their monthly treatment. The animal owner reports that they have been using FRONTLINE SPOT ON for 13 years and has never had a problem. They believe that there is a problem with this particular packet as the dog is now covered in fleas and scratching like mad, despite using it every 4 weeks like clockwork. The animal owner is itching a lot but hasn't had an actual bite yet, but believes that there is an infestation as the animal is covered. The animal owner is using a home spray which they have bought for the entire house. The animal owner isn't bathing the animal or doing anything to affect the efficacy, they seem to be doing everything right. The animal owner has two vials left, and mentioned that the consistency seemed different - not as oily and it didn't leave the fur crispy like it usually does, it seemed to be like water.
23-Oct-2019	UAE; 19UK003559; -; United Kingdom	**Species:** Canine **Breed:** Bichon Frise **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 8.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	N/A	2019*	N/A	D-D	As reported by the animal owner, Benny, a 9 year old male neutered Bichon Frise canine, weighing 8.5 kg and in good condition, was administered FRONTLINE PLUS SPOT ON DOG S (batch S62709BW expiry SEP 2021) topically to an unknown site, by the animal owner, at a dose of 1 dose every 30 days, from an unknown date for an unknown indication. The animal owner reports that they always apply the product throughout the year and is still seeing fleas on the animal's tummy. It has been applied twice by the husband and wife by accident one week ago, and they are considering using a shampoo. The owners are being bitten in the house. Start date added for submission purposes only.
24-Oct-2019	UAE; 19UK003570; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner via Social Media, a female feline (signalment other wise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) (details unknown) for an unknown indication. The animal owner reports that FRONTLINE PLUS does not work on their cat, she still has fleas. Start date added for submission purposes only.
24-Oct-2019	UAE; 19UK003572; -; United Kingdom	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** X **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 6.5 - 8 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	N/A	01-Oct-2019*	N/A	D-D	As reported by the animal owner, Foxy a male aged 14 years and weighing 6.5 kg and Betty a female aged 12 years and weighing 8 kg, both Jack Russell Terrier canines, were given FRONTLINE PLUS SPOT ON DOG S (batch and expiry unknown) on 19 OCT 2019 topically to an unknown site by the animal owner for parasite control. The animal owner reports that they used fog bombs and treatments on 19 OCT 2019 but they treat every 30 days (start date unknown) with FRONTLINE PLUS. The animal owner is still seeing fleas and is being bitten in the home. Foxy is gnawing at his back legs and very agitated. The animal owner will speak to their vet about this. Start date for submission purposes only.

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ED_005739D_00014391-00202

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					
24-Oct-2019	UAE; 19UK003577; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	May-2019*	Sep-2019*	0 Day(s)	D-D	As reported by the animal owner, a female feline (signalment otherwise unknown) was given FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown) from MAY 2019 by the animal owner for parasite control (no further information available). The animal owner reports that they treated the house with all the sprays that the retailer recommended to them (assumed in MAY 2019). The animal owner reports that everything was fine up until SEP 2019, the cat was chewing at her legs and was causing scabs around her neck. They knew that the fleas had to jump onto their cat for them to die, but their cat's behaviour didn't change. Two weeks after putting the treatment on the cat, the animal owner decided to comb through her hair and they found 3 fleas. The animal owner has changed all the bedding, sprayed everywhere, the even gave their cat a flea tablet treatment. As of OCT 2019 it has gotten worse, the animal owner is being bitten whilst they are sleeping, the cat is leaving eggs where she sleeps and her scabs and chewing has got worse. The animal owner has never stopped using the flea treatment, it is supposed to help control the infestation but it doesn't seem to be having any effect anymore.
24-Oct-2019	UAE; 19UK003578; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	21-Oct-2019*	0 Day(s)	D-D	As reported by the animal owner, a male feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) on approximately 21 OCT 2019 for an unknown indication. The animal owner reports that their cat still has fleas 3 days after treatment and asks if they should treat again.
25-Oct-2019	UAE; 19UK003590; -; United Kingdom	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 38.5 - 39 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	15-Oct-2019*	0 Day(s)	D-D	As reported by the animal owner, a 2 year old male German Shepherd canine weighing 38.5-39 kg and in unknown condition, was administered FRONTLINE PLUS SPOT ON DOG L (batch and expiry unknown, details unknown) by the animal owner ten days ago (15 OCT 2019) for an unknown indication. The animal owner reports that they recently switched to using FRONTLINE PLUS on their dog and soon after the switch, they noticed fleas on him. They had him weighed and he is 38.5-39 kg and hence were recommended the 20-40 kg bracket treatment. Since they have treated the animal, the last treatment was 10 days ago, they threw out his bed, have treated the house and yet they still have a flea problem. The animal owner is unimpressed as they have never had a flea problem until now.
26-Oct-2019	UAE; 19UK003594; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown	N/A	Oct-2019*	N/A	D-D	As reported by the animal owner, a female canine (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG L, batch and expiry unknown, details unknown) by the animal owner for an unknown indication. The animal owner reports that they recently used FRONTLINE PLUS for their large female dog, which has failed to work and now as an effect they have fleas in their house. The animal owner feels tremendously let down by the product. On 28 OCT 2019 the animal owner reported that they appreciate the

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ED_005739D_00014391-00203

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					product won't stop fleas jumping on the dog but it generally hasn't worked. The animal owner has given it a week now and there has been no change. The animal owner has recently changed to FRONTLINE PLUS from Advantage and haven't had this issue before. The product has completely failed them. The fleas are very much still there and the animal owner knows they have them in the carpet. Start date added for submission purposes only.
27-Oct-2019	UAE; 19UK003595; Cheshire; United Kingdom	**Species:** Canine **Breed:** Bulldog **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	08-Oct-2019	0 Day(s)	D-C	As reported by the retail outlet salesperson, Roxy, a 2 year old female Bulldog canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) on 08 OCT 2019 for a flea and tick treatment. The salesperson stated that the animal owner has applied FRONTLINE treatment to their dog and the dog has chemical burns on the back. The animal was a pedigree that cost £2500 and now has permanent scarring from the treatment. The customer said that the product smelled strongly of ammonia when they applied it. The animal owner added that their vet has diagnosed this reaction as a chemical burn and not an allergic reaction. They have used the product every month for two years and never had any issues before. After the animal owner had put it on the animal's neck, they noticed that it smelt like ammonia and instantly the animal's skin became bright red and hot, soon followed by blisters. The vets put the animal straight on strong antibiotics (Nisamox) and METACAM pain relief, and an antiseptic wash (Hibiscrub). The animal owner is quite angry that this has happened to their dog and they are very concerned it happens again to their pets or any others in the future. The clinical history for the animal states that the animal was seen on 11 OCT 2019 and that the spot on treatment was applied three days ago. The animal was panting, had a heart rate of 140 bpm, a temperature of 39.4, pink and moist mucous membranes and a capillary refill time of less than 2 seconds. The animal had metatarsal pulses within normal limits and the lymph nodes were within normal limits. The skin was inflamed with a purulent discharge on the dorsal aspect of the neck, extending to the shoulder blades. UPDATE 02 DEC 2019: QA results received. Investigation completed for FIPRONIL SPOT ON DOG Lot UNKNOWN, expiry. Final complaint evaluation An adverse event for Frontline FRONTLINE Spot On Dog, batch unknown, was received by BIAH QA on the 05th of
27-Oct-2019	UAE; 19UK003596; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a female feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) for flea treatment. The animal owner reports that they pay a monthly subscription for the flea treatment and so imagine their surprise when they sat in the kitchen and found a flea on their trousers. The animal owner went and checked the cat and she has fleas. The animal owner has to go out and get treatment for the house and the animal, which they do not think is right. Start date added for submission purposes only.
28-Oct-2019	UAE; 19UK003598; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown)	3	3	0	**Product used:** FIPRONIL SPOT ON DOG	N/A	Oct-2019*	N/A	D-D	As reported by the animal owner, three canines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown,

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ED_005739D_00014391-00204

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					details unknown) by the animal owner last week (estimated OCT 2019) when they got infested with fleas. The animal owner reports that they spotted a very healthy looking flea running through their dogs hair. They treated all their dogs at the same time and they are still scratching. The animal owner has washed the bedding etc.
28-Oct-2019	UAE; 19UK003602; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	26-Oct-2019	26-Oct-2019	0 Day(s)	D-D	As reported by the animal owner, Missy a neutered female feline aged 12 years (signalment otherwise unknown) was given FRONTLINE SPOT ON CAT (batch and expiry unknown) on 26 OCT 2019 topically by the animal owner as a parasiticide. The animal owner had seen live fleas on the cat. On 28 OCT 2019 the animal owner reported that they were still seeing fleas on the cat. The cat was not treated previously with any flea products and was therefore unprotected. The cat is an indoor cat and does go into the garden. The animal owner's 4 year old child is being bitten and there are fleas in her bed. The animal owner treated the house yesterday (27 OCT 2019) with StayKill spray.
28-Oct-2019	UAE; 19UK003604; Avon; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** Bob Martin flea tablet; Bob Martin flea spray; Flea powder; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	01-Oct-2019*	N/A	D-D	As reported by the retailer, approximately 2 felines (signalment otherwise unknown) were given FRONTLINE SPOT ON CAT (batch number S21715AL expiry date OCT 2021) by the animal owner as a parasiticide (no further information available). The retailer reports that the animal owner had contacted them to say that the product is not working. The animal owner has treated their house with Bob Martin flea spray and also a powder. The animal owner is vacuuming daily and steam cleaning furniture. The animal owner has also given a Bob Martin tablet to kill fleas before treating with FRONTLINE. The animal owner has used the product before and it has worked just this time nothing seems to work. The cats are house cats and do not go outside. Start date for submission purposes only. UPDATE 23 DEC 2019: QA results received. Investigation completed for FIPRONIL SPOT ON CAT Lot S21715AL, expiry 2021-10-31. Final complaint evaluation BIAH QA received a product quality complaint for FRONTLINE Spot on Cat, batch S21715AL, on the 07th of November 2019. The complaint description is lack of efficacy. This is the first complaint regarding this defect for this batch. Not reviewed : the retention sample is stored for identification purposes. Therefore, it is not applicable to this kind of defect. The complaint sample is not received. No picture is attached for this case. Batch record investigation: Bulk batch S217 :Manufacturing date: 20/11/2018 - Expiry date: N/A - Manufacturing quantity: 1199 liters. No deviation and observation are associated to this batch. This batch was not concerned by any change control. The results of QC testing are conform to specifications. All the parameters verified during the manufacturing of this batch of bulk are conform. Filling batch S21715 : Manufacturing date: 07/12/18. Expiry date: 10/2021 - Manufacturing quantity: 117 860 pipettes. No deviation associated to this batch. Two observations are associated to this batch unrelated to this defect. This batch was
28-Oct-2019	UAE; 19UK003606; East Sussex; United Kingdom	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	29-Sep-2019	29-Sep-2019	0 Day(s)	D-D	As reported by the animal owner, Marmite a neutered male Domestic Shorthair feline aged 12 years and in good condition (weight unknown), was given FRONTLINE PLUS SPOT ON CAT (batch number S41306AW expiry date OCT 2021) topically to an

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ED_005739D_00014391-00205

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: M **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** Unknown				12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					unknown site at a dose of one dosage form monthly since the cat was a kitten (estimated starting in 2007) by the animal owner for parasite control. The animal owner reports that they treat the cat every month all year round. The cat was treated on 27 JUL 2019 and 30 AUG 2019 with a previous batch of FRONTLINE PLUS (batch number and expiry not known) and the cat was treated with batch number S41306AW on 29 SEP 2019 and 24 OCT 2019. The cat has been covered in fleas since using the new batch on 29 SEP 2019 and the owner is being bitten. The animal owner gave the last treatment a few days early due to seeing so many fleas. The animal owner has washed all bedding, soft furnishings and hoovers every day and empties the hoover every time. The house was treated two weeks ago. UPDATE 18 DEC 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot S41306AW, expiry 2021-10-31. Final complaint evaluation A product quality complaint for FRONTLINE PLUS SPOT ON CATS, batch number S41306AW was received by BIAH QA on the 07th of November 2019. The complaint description is: LOE. This is the second complaint regarding this kind of defect for this batch. The complaint sample is not received. Pictures are not attached for this case. Not reviewed : the retention sample is stored for identification purposes. Therefore, it is not applicable to this kind of defect. Batch record review: S413. Manufacturing date: 06/11/2018. Expiry date: NA. Manufacturing quantity: 999 liters. Associated deviation(s): No deviation associated to this batch. Change control associated: This batch was not concerned by any change control. Observation(s): No observation associated to this batch. Results of QC testing: Conform at
29-Oct-2019	UAE; 19UK003609; Kent; United Kingdom	**Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** F **Sex qualifier:** Lactating **Age:** 3.16 Year(s) **Weight:** 25 kg*	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	29-Oct-2019	22 Day(s)	D-D	As reported by the veterinary nurse, Sasha, a 3 year and 2 month old female lactating Labrador canine weighing approximately 25 kg and in good condition received FRONTLINE SPRAY (batch number and expiry date unknown) on 07 OCT 2019, administered topically by the animal owner at an unknown dose to treat fleas. The animal has received the product before on unknown dates. The owner requested that the vet report that he is still seeing fleas. The customer is a breeder and always uses FRONTLINE SPRAY on his dogs. He believes this time it is not working because he is seeing fleas. He has treated the brood bitch once because he saw fleas and has not treated the puppies. The owner refuses to use a household flea spray.
29-Oct-2019	UAE; 19UK003617; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Aug-2019	Oct-2019*	N/A	D-D	As reported by the animal owner Aragorn (17 years old), Darwin (17 years old) and Tiddles (12 years old), all felines of unknown signalment and of unknown weight and condition received FRONTLINE SPOT ON (assumed CAT), from AUG 2019 at 4 week intervals, applied topically by the animal owner. Pippin, a 15 year of Jack Russell Terrier is kept with the cats and was also treated with FRONTLINE SPOT ON (assumed DOG). All the animals are fit and well and were previously on Advocate . The animals were started on FRONTLINE SPOT ON, which was administered to all 4 pets in the last two months. There are no bites to the owners but the owner reports very high numbers of live fleas seen on the cats. The owner has treated the whole house and hot washed the bedding. Start date added for submission purposes.

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ED_005739D_00014391-00206

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
29-Oct-2019	UAE; 19UK003618; South Yorkshire; United Kingdom	**Species:** Canine **Breed:** West Highland White **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 8 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL SPOT ON DOG; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Sep-2019*	2019*	N/A	D-D	As reported by the animal owner, Daisy, an 11 year old female neutered West Highland White Terrier canine, weighing 8 kg and in good condition, was administered FRONTLINE PLUS SPOT ON DOG S (batch and expiry unknown) topically to an unknown site, by the animal owner, at a dose of 1 pipette every 4 weeks for flea prevention. The animal owner reports that the animal has used FRONTLINE SPOT ON DOG S since a puppy (estimated since 2017) and that the last two treatments have been FRONTLINE PLUS (applications estimated to be SEP 2019 and OCT 2019). The animal has been to the groomers who noticed evidence of fleas. The animal owner sprayed the house 6 weeks ago (product unknown) and washed bedding on a hot wash. The animal owner was shutting the animal out of bedrooms. Start date added for submission purposes only.
29-Oct-2019	UAE; 19UK003625; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	5	5	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	21-Oct-2019	0 Day(s)	D-D	As reported by the animal owner, five felines (signalment otherwise unknown) were administered FRONTLINE SPOT ON CAT, Batch and expiry unknown, details unknown by the animal owner a week ago (21 OCT 2019) for an unknown indication. The animal owner reports that they still seem to be scratching. The animal owner reports that they also have 4 dogs (see linked case 19UK003626). The animal owner treats the pets when they see fleas, they use the product all year round, they last used the product on 21 OCT 2019, the animal owner doesn't know the last four dates they applied the product, they applied it spot on between the shoulder blades, people in the home are not being bitten by fleas, the pets spend time indoors and outdoors, all animals in the home have been treated, the animal owner hasn't seen fleas but there is evidence of flea dirt in the pets' fur, the pets have not been bathed or gone swimming within 2 days of product application, the animal owner has not lived in the home for less than a year, they have treated the home with an environmental flea treatment and all areas the pets can access have been regularly vacuumed.
29-Oct-2019	UAE; 19UK003626; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	21-Oct-2019	0 Day(s)	D-D	As reported by the animal owner, four canines (signalment otherwise unknown) were administered FRONTLINE Spot On Large Dog (>20-40 kg), Batch and expiry unknown, details unknown) by the animal owner a week ago (21 OCT 2019) for an unknown indication. The animal owner reports that they still seem to be scratching. The animal owner reports that they also have 5 cats (see linked case 19UK003625). The animal owner treats the pets when they see fleas, they use the product all year round, they last used the product on 21 OCT 2019, the animal owner doesn't know the last four dates they applied the product, they applied it spot on between the shoulder blades, people in the home are not being bitten by fleas, the pets spend time indoors and outdoors, all animals in the home have been treated, the animal owner hasn't seen fleas but there is evidence of flea dirt in the pets' fur, the pets have not been bathed or gone swimming within 2 days of product application, the animal owner has not lived in the home for less than a year, they have treated the home with an environmental flea treatment and all areas the pets can access have been regularly vacuumed.
30-Oct-2019	UAE; 19UK003638; -; United Kingdom	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other	N/A	2019*	N/A	D-D	As reported by the animal owner, a female Chihuahua canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG S, batch and expiry unknown) for flea treatment. The animal owner reports that they bought a three month supply and it didn't work. The animal still has

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ED_005739D_00014391-00207

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - **Weight:** Unknown				products **Route:** unknown **Was the product used ok?:** Unknown to Company					fleas, and the animal owner thinks that it is a lot of money if it is not going to work. Start date added for submission purposes only.
30-Oct-2019	UAE; 19UK003645; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** Johnson's Room Foggers; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	29-Sep-2019	29-Sep-2019	0 Day(s)	D-D	As reported by the animal owner, Saffron, a 15 year old female feline weighing 6 kg (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch and expiry unknown) topically to the back of the neck, between the shoulder blades and then also slightly further back, by the animal owner on 29 SEP 2019 for fleas. The animal owner reports that their house cat had the misfortune of getting fleas, obviously they must have been brought into the house by a different means and they have then found her. The animal owner bought FRONTLINE as when they first got the animal as a kitten 15 years ago, the animal came with fleas and FRONTLINE cleared everything up. The animal owner applied everything as directed and unfortunately found that it has not made any difference. The animal has scratched herself until she has bald patches and due to the warning about overdosing, the animal owner was unable to do anything more. They treated the house too, but sadly this may now have been in vain as the FRONTLINE hasn't worked and so she may have just been spreading them round again. Due to the first FRONTLINE treatment making very little difference to the animal , the animal owner went to the vet instead and has been prescribed a treatment, which has left the animal entirely flea free in just 4 hours. The animal owner reports that they have completely wasted the money and their cat has had to endure distress during the last 4 weeks whilst it has failed to work. The animal owner is incredibly disappointed in the product. The animal owner added that the animal is a house cat and they treat only when they see fleas, and she has only had fleas once. The animal owner started using the product for their flea issue 5 weeks ago. People in the home are being bitten by fleas, all animals in the household and in contact animals have been treated and the animal owner hasn't seen fleas but there is flea dirt and evidence of fleas in the animal's fur. The animal owner has treated the home
31-Oct-2019	UAE; 19UK003660; Cheshire; United Kingdom	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.17 Year(s) **Weight:** 23.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Itch Pet Spot on; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	22-Oct-2019*	8 Day(s)	D-D	As reported by the retail outlet, Munchies, a 1 year 2 month old male neutered Staffordshire Bull Terrier cross canine , weighing 23.5 kg and in unknown condition, was administered FRONTLINE PLUS SPOT ON DOG M (batch and expiry unknown, details unknown) by the animal owner on 14 OCT 2019 for fleas. The animal owner had previously applied Itch Pet Spot on 28 SEP 2019. The animal owner took the animal to the vet on 26 OCT 2019 as they were still seeing live fleas even now, and the animal had been lethargic since the other product was applied (on 28 SEP 2019). The animal had had gastrointestinal signs for the last 3 to 4 days (estimatd start date 22 OCT 2019) and had not eaten much but that this was improving slowly now. The animal vomited 2 days ago and hadn't since, but the poos were runny but now formed. The animal owner thinks that the animal is slightly better. On examination the animal was lively with a normal temperature, pulse and respiratory rate. The animal's mucous membranes were pink, capillary refill time less than 2 seconds and no petechia was seen. The teeth were clean with slightly crooked incisors. The lymph nodes palpated as normal, the chest clear and no abdominal pain

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ED_005739D_00014391-00208

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											or thickenings felt. There were live fleas seen and some small raised areas in the coat that were papular, located on top of the head. This case is classified as both 'SLEE' and 'Adverse Reaction' but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse Reaction', has been transmitted.
31-Oct-2019	UAE; 19UK003669; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, two felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT) (batch and expiry unknown) (details unknown) by the animal owner for an unknown indication. The animal owner reports that they recently bought two packs of three flea repellent applications and from the start their kittens have still been scratching. They have made no difference. The animal owner has had cats all their life and used the product a lot. Each time they have used the treatment recently they have still been scratching. There are still fleas on their partially white cat and blatant eggs on their black cat. That is not good enough. Start date added for submission purposes only.
31-Oct-2019	UAE; 19UK003670; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, 4 cats of unknown signalment, weight and condition received FRONTLINE PLUS SPOT ON CAT on an unknown dates. The owner reports they purchased the product for their 4 cats and they are chewing, washing, sucking, scratching worse than they have ever seen them before. The owner is very upset by this as they cannot afford to buy products that make their poor pets really uncomfortable and irritated. The owner reported that the cats are house cats and do not mix with other animals and that they are now riddled (assumed with fleas). Start date added for submission purposes only. This case is classified as both 'SLEE' and 'Adverse Reaction' but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse Reaction', has been transmitted.
02-Nov-2019	UAE; 19UK003689; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** RIP Flea Spray; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	01-Nov-2019	6 Day(s)	D-D	As reported by the animal owner, one Lurcher canine (signalment otherwise unknown) was administered FRONTLINE SPOT ON DOG M (batch and expiry unknown, details unknown) on 26 OCT 2019 for flea treatment. The animal owner reports that they are really not impressed with the flea treatment that they bought. They treated their dog as usual on 26 OCT 2019 with the FRONTLINE and hoovered, bleached and sprayed the whole house and garden with RIP Flea Spray. They have no carpets, vinyl flooring, and they threw out a leather sofa. The animal owner reports that they took their animals to the groomers yesterday 01 NOV 2019 and was mortified when the groomer informed them that they had live fleas on them. They have never had this problem before and they are not at all impressed.
02-Nov-2019	UAE; 19UK003690; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** RIP Flea Spray;	N/A	01-Nov-2019	6 Day(s)	D-D	As reported by the animal owner, three little canines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON DOG S (batch and expiry unknown, details unknown) on 26 OCT 2019 for flea treatment. The animal owner reports that they are really not impressed with the flea treatment that they bought. They treated their three little dogs as usual on 26 OCT 2019 with the FRONTLINE and hoovered, bleached and sprayed the whole house and garden with RIP Flea Spray. They have no carpets, vinyl flooring, and they threw out a leather sofa. The animal owner

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ED_005739D_00014391-00209

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: unknown **Was the product used ok?:** Unknown to Company					reports that they took their animals to the groomers yesterday 01 NOV 2019 and was mortified when the groomer informed them that they had live fleas on them. They have never had this problem before and they are not at all impressed.
02-Nov-2019	UAE; 19UK003691; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** Indorex; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a female feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) by the animal owner for an unknown indication. The animal owner reports that when they acquired a cat last year they started using the product on her. The problem is that the animal now has fleas. The animal owner applied FRONTLINE to the animal and manually removed the fleas. They brushed the animal daily with a nit comb for 2 weeks, removing fleas as they went along and then applied the FRONTLINE again. The animal owner hoovered daily, paying attention to the skirting boards and threw out the animal's bed. They have also used Indorex spray. The animal owner is still finding fleas on the animal. Start date added for submission purposes only.
02-Nov-2019	UAE; 19UK003692; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** Indorex; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown, details unknown) by the animal owner for an unknown indication. The animal owner reports that they have been using the product for 10 years on their dog with no issues. The problem is that the animal now has fleas. The animal owner applied FRONTLINE to the animal and manually removed the fleas. They brushed the animal daily with a nit comb for 2 weeks, removing fleas as they went along and then applied the FRONTLINE again. The animal owner hoovered daily, paying attention to the skirting boards and threw out the animal's bed. They have also used Indorex spray. The animal owner is still finding fleas on the animal. Start date added for submission purposes only.
03-Nov-2019	UAE; 19UK003693; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	30-Oct-2019	0 Day(s)	D-D	As reported by the animal owner, Ziggy, a male feline (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner on 30 OCT 2019 for an unknown indication. The animal owner reports that the animal is still licking furiously at times and there is still flea dirt in his fur. The animal owner wants to re-treat him.
04-Nov-2019	UAE; 19UK003696; Wiltshire; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 9 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL SPOT ON DOG; **Route:** Topical / Cutaneous	21-Oct-2019	04-Nov-2019	2 Week(s)	D-D	As reported by the animal owner, Ellie, a 5 year old female neutered canine weighing 9 kg and in good condition (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG S, batch and expiry unknown) topically to an unknown site by the animal owner, at a dose of 1 pipette on 21 OCT 2019 for a preventative treatment. The animal owner reports that they applied it two weeks ago and they are still seeing a few fleas this morning. Before using FRONTLINE PLUS the animal received FRONTLINE SPOT ON (assumed FRONTLINE SPOT ON DOG S) monthly. The house has never been treated and there could have been a couple of

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ED_005739D_00014391-00210

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					days where the animal's treatment was delayed. The animal owner reported that there is also a new cat in the house as well, that has been rescued and only had it's first treatment last week.
04-Nov-2019	UAE; 19UK003701; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown, details unknown) by the animal owner at a dose of 2 pipettes in two weeks, for an unknown indication. The animal owner reports that they are sending a complaint about the product that they recently purchased from an online trusted store for their dog. According to the advert on TV the new PLUS product will target eggs as well, but unfortunately they ended up using two pipettes in two weeks and still there was not much improvement. The animal owner was very satisfied with the original one but this new one is not working and they are not happy paying for something that doesn't work. Start date added for submission purposes only.
04-Nov-2019	UAE; 19UK003710; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	Oct-2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch and expiry unknown, details unknown) as an anti-flea treatment. The animal owner reports that they wish to express their disappointment in the product. They have been buying this anti-fleas treatment for their cat for many years, and it has been working fine until recently. A few weeks ago their cat became infested with fleas and as a result the entire house had to be treated. Their vet recommended another spot on anti-flea product, which worked within 48 hours. They also informed the animal owner that after some changes in the FRONTLINE formula, this product doesn't work anymore and numerous clients had similar issues to the animal owner.
05-Nov-2019	UAE; 19UK003712; -; United Kingdom	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	N/A	29-Oct-2019	0 Day(s)	D-D	As reported by the animal owner, Ruby, a 4 year old female neutered Domestic Short Hair feline, weighing 6 kg and in good condition, was administered FRONTLINE PLUS SPOT ON CAT (batch S41303AW expiry OCT 2021) topically to an unknown site, by the animal owner on 29 OCT 2019 as they saw fleas and the animal was scratching. The animal owner has used two pipettes within 30 days and they are still seeing fleas. The animal owner is being bitten and they have sprayed Staykill.
05-Nov-2019	UAE; 19UK003714; Devon; United Kingdom	**Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 31 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL SPOT ON DOG; **Route:** Topical / Cutaneous **Was the product used**	Apr-2019*	03-Nov-2019	6 Day(s)	D-C	As reported by the animal owner, Finn, born 04 JUN 2011, a male neutered Labrador Retriever canine, weighing 31 kg and in good condition, was administered FRONTLINE PLUS SPOT ON DOG L (batch S62911 expiry SEP 2021) topically by the animal owner, at a dose of 1 dose, on 28 OCT 2019 for preventative care. The animal last had this product 6 months ago and normally uses FRONTLINE SPOT ON (assumed FRONTLINE SPOT ON DOG L). On 03 NOV 2019 the animal owner noticed that the fur around the application site looked a little greasy but they didn't notice anything concerning. 24 hours later, 04 NOV 2019, they checked again and noticed an infection. They found two nasty wounds over his shoulders. In the evening they took the animal to see the vets who shaved and cleaned the area, administered a steroid injection

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ED_005739D_00014391-00211

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					(Dexafort 2.5 ml via SC injection), dispensed Rilexine Tablets 600 mg twice daily and antibiotics and advised to bathe it twice daily with Hibiscrub. The animal owner cannot be sure that the areas that are red/angry/infected are definitely where they applied the product. They do not seem to think that it is where they usually apply it plus the animal did have rough mouthy games with his dog friend last Friday so it possibly could be bite marks that possibly got infected. The animal owner reported that the vet did notice that it looks like the animal had some sort of allergic reaction as there are quite a few little red lumps around the area they clipped. The animal owner added that the animal doesn't appreciate having FRONTLINE PLUS put on but he doesn't go nuts trying to scratch or anything after the animal owner has put it on. The animal didn't actually give any indication he had the two wounds on the animal's shoulders. On 14 NOV 2019 the owner reported that the dog had been taken back to the vets and had confirmed that the dog was now better and had recovered. UPDATE 06 NOV 2019: The batch number for FRONTLINE PLUS SPOT ON DOG L was confirmed as S62911AX. The animal
05-Nov-2019	UAE; 19UK003715; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	Aug-2019*	N/A	D-D	As reported by the animal owner, two canines (signalment otherwise unknown) were administered FRONTLINE SPRAY (batch and expiry unknown, details unknown) for an unknown indication. The animal owner reports that they have spent a lot of money on FRONTLINE products - firstly in the bottle to spray on your dog, and then the FRONTLINE PLUS SPOT ON (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown). After treating their dogs they have not been rid of fleas. Their bed area has been changed and cleaned on a high temperature and treated (they saw no evidence of fleas there but treated anyway). Both dogs still have fleas and they have been trying to tackle it since AUG 2019. The animal owner asks if the product changed it's ingredients as they used it successfully many years ago.
06-Nov-2019	UAE; 19UK003724; -; United Kingdom	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** RIP House spray; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Jun-2019*	06-Nov-2019*	N/A	D-D	As reported by the attending veterinary surgeon, Fluffy a 3 year old, neutered female Domestic Shorthaired cat, of unknown weight, was treated with FRONTLINE PLUS SPOT ON CATS (batch number: T40208A and expiry date: JAN 2022) at an unknown dose, applied topically by the owner from approximately JUN 2019 applied monthly on the 15th of each month because the owner had seen fleas. On 06 NOV 2019 the owner reported that they were still seeing fleas and flea eggs, but the eggs could have been flea dirt. The owner also reported that they had also used RIP house spray 4 months ago (date estimated as JUL 2019). The owner hovered daily and had washed bedding. The cat went outside as well as inside but was not allowed upstairs. The owner was not seeing fleas in the house however, only on the cat. The cat had not been taken to the vet.
06-Nov-2019	UAE; 19UK003725; East Riding of Yorkshire; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Week(s) **Weight:** 1.48 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous	01-Nov-2019	06-Nov-2019	5 Day(s)	D-D	As reported by the veterinary nurse, Blue a 9 week old male entire feline, weighing 1.48 kg (signalment otherwise unknown) was administered FRONTLINE SPRAY (batch and expiry unknown, details unknown) topically by the breeder on 01 NOV 2019 for preventative care. The veterinary nurse reports that the animal was in for a vaccination today and still has live fleas. They are not 100 percent sure which product was applied as the breeder's notes just say FRONTLINE.

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Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					
06-Nov-2019	UAE; 19UK003726; Lancashire; United Kingdom	**Species:** Canine **Breed:** Tibetan Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 17 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dexafort; Prednisolone; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	07-Sep-2019	07-Oct-2019	30 Day(s)	D-C	As reported by the attending veterinary surgeon, Teddie, a 4 year old male neutered Tibetan Terrier canine, weighing 17 kg and in good condition, was administered FRONTLINE PLUS SPOT ON DOG (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown, details unknown) topically by the animal owner on 07 SEP 2019 as a parasiticide. On 07 OCT 2019 the animal presented at the emergency vets with a severe cutaneous reaction. This started with a small blister and the animal was very pruritic. The groin and ventrum were very red. The animal was given Dexafort (0.3 ml injection) and this was followed the next day by Prednisolone oral (5 mg once daily for 5 days and then 5 mg every other day). On 06 NOV 2019 the animal still had inflammation in the groin region, and it appears infected with a purulent discharge. The animal was given a buster collar to stop the self trauma due to pruritus.
06-Nov-2019	UAE; 19UK003727; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Insecticidal household flea product; **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	06-Nov-2019	6 Day(s)	D-D	As reported by the animal owner via an online advice tool, a cat (signalment otherwise unknown), had been treated with FRONTLINE PLUS CAT, 4 weeks ago or less. The product had been bought in a pet shop. On 06 NOV 2019 the owner reported that even though they had treated their pet within the last 3 months, they were still seeing fleas, 5 or more at the same time. The people in the house however, were not being bitten. The owner had treated the home with an insecticidal household flea product, had washed and treated the pets bedding and had vacuumed regularly. The owner reported that the cat never bathed or went swimming.
07-Nov-2019	UAE; 19UK003735; -; United Kingdom	**Species:** Canine **Breed:** Australian Sheep Dog **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 37 - 38 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	31-Oct-2019	31-Oct-2019*	0 Day(s)	D-D	As reported by the animal owner, Chewbacca, a 3 year old female neutered Australian Shepherd Dog Canine, weighing 37-38 kg and in good condition, was administered FRONTLINE SPOT ON DOG L (batch S21601AX expiry OCT 2021) topically by the animal owner, at a dose of 1 dose, on 31 OCT 2019 as part of their monthly treatment. The animal owner reports that they have had some gaps in treatment this year. The animal owner usually used FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG L) but picked up FRONTLINE SPOT ON by accident this time. The animal owner applied FRONTLINE SPOT ON about a week ago but it doesn't seem to be working and the animal still has fleas. The animal owner confirmed that treatment was missed for about a month previously and the animal has also been in contact with other dogs at the beach and has been scratching since. The animal owner has a home spray and is currently tackling all areas. They are seeing a lot of fleas on the dog but not really in the home. The animal owner has one bite but they are not convinced that it is a flea bite. The animal owner is happy to continue with home treatment and monthly spot ons in order to get on top of the problem. UPDATE 04 DEC 2019: The animal owner reported that they

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ED_005739D_00014391-00213

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											checked the animal over yesterday and it still has fleas. There were around 20 fleas taken off the animal, and since last reporting this, the animal owner has used FRONTLINE PLUS instead of FRONTLINE SPOT ON but it is still not working. No one in the house is being bitten however the animal does sleep on the sofa and the other day the animal owner found one flea on their jumper. The animal has been following all recommendations - on time with treatments, washing bedding at over 60 degrees and hoovering. The animal is very itchy where the fleas are and is uncomfortable and biting her legs. The animal does get taken to the beach but does not go in the sea. The animal owner said that their vet told them that fleas were resistant to FRONTLINE.
07-Nov-2019	UAE; 19UK003736; Gwent; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Yes	03-Nov-2019	Nov-2019*	11 Day(s)	D-D	As reported by the animal owner, three canines (signalment otherwise unknown) were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown), details unknown) by the animal owner, at a dose of 1 pipette on 03 NOV 2019 as a parasiticide. This is the first time that the animal owner has used FRONTLINE PLUS and they previously used Bob Martin. The animal owner reported that the product has not worked. The son is being bitten by fleas and the animal owner is extremely angry. The animal owner has not yet treated the house but will, and has hot washed the bedding.
07-Nov-2019	UAE; 19UK003740; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Nov-2019	Nov-2019*	10 Day(s)	D-D	As reported by the animal owner, Luna and Loki, two 9 month felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown) topically by the animal owner, at a dose of 1 pipette on 04 NOV 2019 as a parasiticide. The animal owner is a police officer and went to a house that was flea infested and now has seen live fleas on her two house cats. The animal owner can still see fleas running on both cats. They have sprayed the house and are unsure which FRONTLINE was used.
08-Nov-2019	UAE; 19UK003747; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Sep-2019	19-Oct-2019	within 8 hours	D-D	As reported by the animal owner, Fudge a 14 year old, male neutered cat, was treated with FRONTLINE SPOT ON CAT (batch number: S21509AX and expiry date: SEP 2021), route and frequency unknown, administered by the cat's owner on 29 SEP 2019 and the owner reported that afterwards the cat was fine. The second FRONTLINE SPOT ON CAT dose with the same batch number was given on 19 OCT 2019 and the owner reported that within 8 hours of applying the product, the cat stopped eating and drinking and vomited. Cat recovered within 48 hours, the owner wanted to know if there is anything wrong with the particular batch. UPDATE 19 DEC 2019: QA results received. Investigation completed for FIPRONIL SPOT ON CAT LotS21509AX, expiry 2021-09-30. Final complaint evaluation BIAH QA received a product quality complaint for FRONTLINE spot on cat, batch S21509AX, on 18 nov 2019. The complaint description is an adverse event. This is the first complaint for this packaging batch (AX). However, a previous complaint for the same bulk/filling batch S21509 (packaging BX) was received for a lack of efficacy. The retention sample is conform (aspect). The sample complaint is not received, nor pictures. Batch record investigation: bulk batch S215 Manufacturing date: 17/10/2018 - Expiry date: 09/2021 -

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ED_005739D_00014391-00214

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											Manufacturing quantity: 1199.4 liters. No deviation is associated to this batch and one observation is not associated to this defect. This batch was not concerned by any change control. The results of QC testing are conform at specifications (particularly density). All parameters verified during manufacturing of this batch of bulk are conform. Batch record investigation: filling batch S21509. Manufacturing date: 06/11/2018. Expiry date: 09/2021 - Manufacturing quantity: 165380 blisters. No deviation is associated to this batch and one observation is not associated to this defect. This batch was not concerned by any change control. The results of QC testing are conform at specifications
08-Nov-2019	UAE; 19UK003760; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Oct-2019*	Oct-2019*	0 Day(s)	D-D	As reported by the animal owner, Molly, a female neutered canine in good condition, was administered FRONTLINE SPOT ON DOG (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown, details unknown) topically, by the animal owner, at a dose of 1 pipette in OCT 2019 as they saw fleas. The animal got fleas SEP 2019 and the animal owner bought a Bob Martin product. They applied that and the fleas went away. Four weeks later the animal owner saw more fleas and they applied FRONTLINE. It has not worked and they are still seeing fleas on Molly. The animal owner doesn't treat the animal year round, only when they see fleas. The animal owner has spoken to the vets who have advised that FRONTLINE doesn't work any more and so they are going to get a different product.
08-Nov-2019	UAE; 19UK003762; -; United Kingdom	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 35 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** Unspecified Pet healt plan product (flea treatment); **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	31-Jul-2019	04-Nov-2019	2 Day(s)	D-D	As reported by the animal owner, Ruby, a 7 year old female German Shepherd Dog canine weighing 35 kg (signalment otherwise unknown) was administered FRONTLINE SPOT ON DOG L) (Batch and expiry unknown) (details unknown) topically to the back of the neck, by the animal owner monthly for an unknown indication. The animal owner reports that the animal got fleas when they use FRONTLINE every month. The animal has had a really rough time with it all. The animal owner reports that the last four dates that they applied the product were 31 JUL 2019, 28 AUG 2019, 30 SEP 2019 and 02 NOV 2019. They first noticed fleas on their pet on 04 NOV 2019 and they use the product all year round. The animal spends time indoors and outdoors and in the animal owner's workplace. All animals that live in the household and in contact animals are treated with a flea product, the animal owner is seeing occasional fleas - less than 5 at a time, and the animal is bathed or swims no more than once a week. The animal owner has treated the home with an environmental flea spray, washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pet can access. The animal owner reports that they used FRONTLINE regularly then tried the health plan product (product unknown) but it left the animal's hair all white and so went back to FRONTLINE. This case is classified as both 'SLEE' and 'Adverse Reaction' but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse Reaction', has been transmitted.
08-Nov-2019	UAE; 19UK003763; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown	3	3	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** House Spray	N/A	2019*	N/A	D-D	As reported by the animal owner, three felines (signalment otherwise unknown) were administered FRONTLINE SPOT ON CAT (batch and expiry unknown) (details unknown) by the animal owner for an unknown indication. The animal owner also used a House Spray and they report that they have done all the correct steps as advised by their vet to make sure that the whole house is

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ED_005739D_00014391-00215

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		Age: - **Weight:** Unknown				(unspecified); **Route:** unknown **Was the product used ok?:** Unknown to Company					free of lice, eggs and larvae. They have repeated the steps over a six week period. They are very disappointed that the product did not work and all three of the cats are still itching and the animal owner's family and the animal owner are covered in flea bites. The animal owner is in a predicament where they will have to seek medical advice for themself and the family and also find a different product and brand. Start date added for submission purposes only.
11-Nov-2019	UAE; 19UK003772; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a female feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) by the animal owner, at a dose of 1 dose monthly for an unknown indication. The animal owner reports that they have been using FRONTLINE once monthly on their cat but would like advice on how to soothe or eradicate the lumps that still remain on the skin afterwards. The animal feels scabby and lumpy under the fur. Start date added for submission purposes only.
11-Nov-2019	UAE; 19UK003774; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	03-Nov-2019*	Nov-2019*	9 Day(s)	D-D	As reported by the animal owner, four felines, one of which is female (signalments otherwise unknown) were given FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) by the animal owner 9 days ago (approximately 03 NOV 2019) as a parasiticide (no further details available). The animal owner reports that they bought the product 9 days ago as one of their cats had a couple of fleas on her. The animal owner was told this was the best product to buy so they flead all their cats and treated the house. But the cats are still scratching and have fleas, this has never happened before. The animal owner has already had to buy yet more flea stuff and house stuff. Start date for submission purposes only.
11-Nov-2019	UAE; 19UK003776; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	09-Nov-2019	23 Day(s)	D-D	As reported by the animal owner, two canines (signalment otherwise unknown) were given FRONTLINE SPOT ON DOG (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) on 17 OCT 2019 by the animal owner for parasite control (no further information available). The animal owner reports that they also thoroughly cleaned the house and used FRONTLINE household spray (assumed FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY, batch and expiry unknown). Two days ago (09 NOV 2019) the animal owner discovered a flea on their smallest dog, and yesterday (10 NOV 2019) and today the animals owners have found some more and been bitten themselves overnight. The animal owner states the last treatment seems to have been ineffective. It has not been 30 days since their last treatment but the animal owners are itching.
11-Nov-2019	UAE; 19UK003778; -; United Kingdom	**Species:** Canine **Breed:** Border Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 12.9 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous	N/A	06-Nov-2019	5 Day(s)	D-C	As reported by the animal owner, Theo, a neutered male Border Terrier canine aged 4 years and weighing 12.9 kg, and in good condition, was given FRONTLINE SPOT ON DOG (assumed FRONTLINE SPOT ON DOG M, batch number S20224AL expiry date JAN 2021) on 01 NOV 2019 topically to an unknown site by the animal owner to prevent ticks. The animal owner reports that on 06 NOV 2019 they noticed the area was burnt and there was a weeping wound, the skin around the neck is raised and the hair at

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Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014391-00216

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					the application site has dropped out. The animal owner has applied Hibiscrub and has been cleaning the wound and applying Sudocream to the area. The animal owner says its looking better but thinks it may take about 3 weeks to heal.
11-Nov-2019	UAE; 19UK003784; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL SPOT ON CAT; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately two felines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner, at a dose of 1 dose every 4 weeks for an unknown indication. The animal owner reports that they want to complain in regards to the FRONTLINE PLUS for cats that the stores push you to buy 'with all the benefits and better than normal FRONTLINE.' They have purchased FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown) for years and then went on to buy FRONTLINE PLUS, spending hundreds of pounds. This year the animal owners indoor cats have really suffered, 2019 has nearly finished and the animal owner's cats are worse than ever with fleas. The animal owner uses the product religiously every 4 weeks, vacuums 4 to 5 times a week and also sprays the whole house with a non FRONTLINE product, which has fantastic reviews. The animal owner is really disappointed with FRONTLINE and feels for their animals not being treated properly by the product, having to suffer. The animal owner reports that it is not cheap and after looking online they see terrible reviews for FRONTLINE PLUS. The animal owner won't be purchasing any FRONTLINE products anymore, the trust has truly gone.
11-Nov-2019	UAE; 19UK003786; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately two felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) by the animal owner for an unknown indication. The animal owner reports that they recently purchased FRONTLINE and they are not happy with the product. They have bought this several times and had no issues, but this time it hasn't helped the animals one bit. The animal owner doesn't know if there has been a problem with the product but it seems to have not helped the cats like the previous times. Start date added for submission purposes only.
12-Nov-2019	UAE; 19UK003787; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	Oct-2019*	0 Day(s)	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner, 5 weeks ago or less, for an unknown indication. The animal owner reports that they used the product but it doesn't seem to have resolved the problem. All the pets have been treated for fleas, the pets are never bathed nor go swimming and people in the home are being bitten by fleas. The animal owner treats the home with an insecticidal household flea product, washes and treats the pets bedding and vacuums regularly. Start date added for submission purposes only.
12-Nov-2019	UAE; 19UK003793; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** FRONTLINE PETCARE HOME AND	N/A	2019*	N/A	D-D	As reported by the animal owner, two canines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown, details unknown) by the animal owner, at a dose of 2 doses for an unknown indication. The animal owner reports that they are disappointed. They have used the spray in the flat (assumed FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY, batch and expiry unknown) and two lots of FRONTLINE

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* indicates Approximate date or weight.

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ED_005739D_00014391-00217

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ENVIRONMENT FLEA SPRAY; **Route:** unknown **Was the product used ok?:** Unknown to Company					on both their dogs and they still have fleas. Start date added for submission purposes only.
12-Nov-2019	UAE; 19UK003794; -; United Kingdom	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	09-Nov-2019	0 Day(s)	D-D	As reported by the animal owner, three Jack Russell Terrier canines (signalment otherwise unknown) were administered FRONTLINE SPOT ON (assumed FRONTLINE SPOT ON DOG S, batch and expiry unknown, details unknown) by the animal owner on 09 NOV 2019 as they saw fleas. They animals were treated on Saturday and they are still seeing lots of fleas on the dogs. The animals are not regularly treated - the animal owner cannot remember the last time that they were treated. The animal owner said that there was no smell at all to the product and that they thought that it was supposed to smell. The animal owner said that it was like putting water on, and that it used to have a strong smell.
12-Nov-2019	UAE; 19UK003795; -; United Kingdom	**Species:** Canine **Breed:** Pointer **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 24 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Oct-2019*	Oct-2019*	0 Day(s)	D-D	As reported by the animal owner, Harlequin, a 2 year old female neutered Pointer cross canine, weighing 24 kg and in good condition, was administered FRONTLINE SPOT ON (assumed FRONTLINE SPOT ON DOG L, batch S21403 expiry SEP 2021, details unknown) topically by the animal owner, two and a half weeks ago (OCT 2019) at a dose of 1 pipette for an unknown indication. The FRONTLINE was applied a couple of weeks ago and a couple of days later, the animal owner noticed little lumps come up on the skin at the application site. The animal owner was monitoring them and they got bigger and bigger. In the last couple of days they have scabbed over, the scabs have fallen off and left a red, itchy and uncomfortable looking area that is now bald. There are two separate areas. The animal was taken to the vet today who said that the area was clean and healing and gave them some Vet Gold cream for dry and damaged skin.
13-Nov-2019	UAE; 19UK003797; -; United Kingdom	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 4.9 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	04-Nov-2019	04-Nov-2019	within 6 hours	D-D	8 year old 4.9 kg male neutered DSH cat had Frontline Plus spot on applied on 4 Nov 2019. Diarrhoea and vomiting within 6 hours, lasting 24 hours. Nothing further.
13-Nov-2019	UAE; 19UK003803; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately 2 felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT) (batch and expiry unknown) (details unknown) for an unknown indication. The animal owner reports that they spent money on FRONTLINE for their cats and it didn't work and they are not happy. Start date added for

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* indicates Approximate date or weight.

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ED_005739D_00014391-00218

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - **Weight:** Unknown				**Route:** unknown **Was the product used ok?:** Unknown to Company					submission purposes only.
14-Nov-2019	UAE; 19UK003809; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, two canines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown, details unknown) for an unknown indication. The animal owner reports that they always use FRONTLINE but this year it has not worked. They have now treated their animals twice and the fleas are still present - it has not worked after 2 applications plus spray for the house. Start date added for submission purposes only.
14-Nov-2019	UAE; 19UK003810; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) for an unknown indication. The animal owner reports that they always use FRONTLINE but this year it has not worked. They have now treated their animal twice and the fleas are still present - it has not worked after 2 applications plus spray for the house. Start date added for submission purposes only.
14-Nov-2019	UAE; 19UK003812; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Advocate; **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	N/A	D-D	As reported by the animal owner, Arthur a male cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), route and frequency unknown, administered by the cat's owner (date of use estimated as OCT 2019, as the product was purchased on the 03 OCT 2019). The owner reported that after the first week following use the cat started to shake its head really often and clean itself excessively. The cat was taken to the vet and the vet confirmed that the cat had fleas. The owner reported that they had used Advocate before every month and had only switched to FRONTLINE PLUS because they had read so many good reviews about it. The cat was completely healthy beforehand and had never had any fleas and was always given his next dose at every 4 weeks, so was always protected. The owner would not be using FRONTLINE PLUS again as it had made their cat ill and was jeopardizing the cat's health.
15-Nov-2019	UAE; 19UK003824; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	N/A	Nov-2019*	N/A	D-D	As reported by the animal owner, a male cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), applied to the cat's back, administered by the cat's owner on an unknown date and since the product was administered the owner reported that the cat had lost the fur on his back and this area was very tender. The owner had bought several boxes of the FRONTLINE and did not want to use the product again. Date of adverse event added for submission purposes only.

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ED_005739D_00014391-00219

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					
16-Nov-2019	UAE; 19UK003827; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON; **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	Nov-2019*	N/A	D-D	As reported by the animal owner, approximately 2 cats (signalment unknown) received original Frontline (assumed FRONTLINE SPOT ON CAT) for years. The owner found it to be losing effectiveness so bought FRONTLINE PLUS SPOT ON CATS. Used first time and appeared not to work at all, the owner found after a few days all animals still scratching and the owner was able to comb several live fleas and eggs from them. The owner tried treatment for the second time this month and also deep cleaned the house, including carpets, bedding etc. Again after all this the owner is finding the treatment to have had zero effect. Might as well have been water in them. Start date for submission purposes only.
16-Nov-2019	UAE; 19UK003828; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a dog of unknown signalment was treated with FRONTLINE PLUS SPOT ON DOGS S at an unknown dose on an unknown date. Used first time and appeared not to work at all, the owner found after a few days all animals (see linked case GBR-BIAHPV1P-19UK003827) were still scratching and the owner was able to comb several live fleas and eggs from them. The owner tried treatment for the second time this month and also deep cleaned the house, including carpets, bedding etc. Again after all this the owner is finding the treatment to have had zero effect. Might as well have been water in them. Start date for submission purposes only,
17-Nov-2019	UAE; 19UK003829; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Indication not indicated / recommended)	N/A	01-Nov-2019*	0 Day(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOG (estimated as FRONTLINE PLUS SPOT ON DOG M, batch number: S60611AR and expiry date: FEB 2021), route and frequency unknown, administered by the dog's owner recently, as the dog had picked up fox mange (date of last application estimated as 01 NOV 2019) and 17 days later the owner reported that there was no sign of improvement. The owner reported that the last two 3 monthly packs had worried them as the FRONTLINE had normally shown improvement in days.
17-Nov-2019	UAE; 19UK003831; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used**	May-2019*	2019*	0 Day(s)	D-D	As reported by the animal owner, their 3 cats (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown), route unknown, administered once per month, by the cat's owner, for the last 6 months (dates used estimated as MAY 2019 to NOV 2019). The owner also reported that they used hoover powder and hoovered all the time. On 17 NOV 2019 the owner reported that the cats still had fleas. The cats were house cats that did not go outside.

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ED_005739D_00014391-00220

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					
14-Nov-2019	UAE; 19UK003840; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** StayKill household flea sprays; Johnson's Flea Bombs; **Route:** unknown **Was the product used ok?:** Unknown to Company	Sep-2019*	Sep-2019*	N/A	D-D	As reported by the animal owner, their cats, number of cats estimated as 2 (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), route and frequency unknown, administered by the cat's owner on 3 occasion's within the past 2 months (start date estimated as SEP 2019). After the first dose the owner had waited for four weeks to give the second dose, then only waited 2 weeks to give the third dose, as they had not seen any real improvement. The pets were still scratching a lot and live fleas had been found on them when combing the animals. A lot of flea dirt had been found when the owner had brushed the animals and a lot of flea eggs had been found on the surfaces they frequented. The owner had also seen flea eggs falling off the cat's all over the house. Whether inactive eggs or not, it was not clear the fleas were still managing to survive long enough to feed and lay eggs. The owner brushed out the fleas as often as they could (however they took a pause on brushing for three days after treatment to not brush out the FRONTLINE PLUS). The owner had even washed the cats 3 days before the latest batch had been used, to be able to compare progress (they waited three days before application to recover the natural oils on their skin and fur as advised). The owner had also been treating the house regularly by continually spraying the house every other day, flea bombing rooms once a week and hoovering every other day. They had been using StayKill household flea sprays every 2 to 3 days in all rooms. They had also been using Johnson's Flea Bombs (the pink ones) once a week in the rooms and had hot washed all the pet bedding and soft furnishings. They had even been to the launderette to wash some of the larger blankets and throws to make sure they were thoroughly cleaned. The owner also had two heat lamps with sticky pads for catching fleas and were still catching live fleas every day. It appeared after 3 treatments
14-Nov-2019	UAE; 19UK003842; -; United Kingdom	**Species:** Other **Breed:** Ferret **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** StayKill household flea sprays; Johnson's Flea Bombs; **Route:** unknown **Was the product used ok?:** Unknown to Company	Sep-2019*	Sep-2019*	N/A	D-D	As reported by the animal owner, their ferrets, number of ferrets estimated as 2 (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), route and frequency unknown, administered by the ferret's owner on 3 occasion's within the past 2 months (start date estimated as SEP 2019). After the first dose the owner had waited for four weeks to give the second dose, then only waited 2 weeks to give the third dose, as they had not seen any real improvement. The pets were still scratching a lot and live fleas had been found on them when combing the animals. A lot of flea dirt had been found when the owner had brushed the animals and a lot of flea eggs had been found on the surfaces they frequented. Whether inactive eggs or not, it was not clear the fleas were still managing to survive long enough to feed and lay eggs. The owner brushed out the fleas as often as they could (however they took a pause on brushing for three days after treatment to not brush out the FRONTLINE PLUS). The owner had also been treating the house regularly by continually spraying the house every other day, flea bombing rooms once a week and hoovering every other day. They had been using StayKill household flea sprays every 2 to 3 days in all rooms. They had also been using Johnson's Flea Bombs (the pink ones) once a week in the rooms including the ferret cage and had hot washed all the pet bedding and soft furnishings . They had

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ED_005739D_00014391-00221

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											even been to the launderette to wash some of the larger blankets and throws to make sure they were thoroughly cleaned. The owner also had two heat lamps with stocky pads for catching fleas and were still catching live fleas every day. It appeared after 3 treatments over 2 months they were still having very happy fleas living on the animals and the owner seriously doubted the product. The owner was hoping for some sign of improvement by now, after so much money spent. The owner reported on the 14 NOV 2019 that they had
19-Nov-2019	UAE; 19UK003844; West Midlands; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** - **Age:** 10.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL SPOT ON CAT; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	22-Oct-2019	Oct-2019*	N/A	D-D	As reported by the animal owner, Alice a female intact feline aged 10 years and in good condition (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON CAT (batch number S41306AW expiry date OCT 2021) topically to an unknown site by the animal owner for parasite control. The product was first applied on 22 OCT 2019 and repeated on 12 NOV 2019, a week early, as the animal owner didn't think it was working. The animal owner previously used FRONTLINE SPOT ON CAT (batch and expiry unknown) monthly but may have missed a day or two. The cat is an outdoor cat, the animal owner is using a flea comb and finding 10 fleas a night and the owners are being bitten. The house has been treated with a house spray and they are hoovering daily. The animal owners are adamant that FRONTLINE PLUS is the problem as they have never had an issue with FRONTLINE SPOT ON. Start date for submission purposes only.
19-Nov-2019	UAE; 19UK003852; -; United Kingdom	**Species:** Canine **Breed:** Canine various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 23 - 38 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Nov-2019	17-Nov-2019	0 Day(s)	D-D	As reported by the animal owner, two canines, one German Shepherd Dog cross canine unknown weighing 23 kg and one Akita weighing 38 kg, were administered FRONTLINE PLUS SPOT ON DOG L (batch and expiry unknown, details unknown) topically by the animal owner two days ago (17 NOV 2019) for fleas. The animal owner reports that they applied the product two days ago to each dog and neither has had an effect on them . The fleas are still there and the dogs are still scratching. The animal owner had combed and combed the dogs and keeps finding the odd couple of fleas on both dogs. The product hasn't worked for either. The animal owner has thrown the box and the 2 pipettes they used out and they feel that they have wasted their money. The animal owner confirmed that they applied the product correctly and has not bathed the dogs. The animal owner has not used any flea treatment prior to this application for years.
20-Nov-2019	UAE; 19UK003855; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	13-Nov-2019	13-Nov-2019	0 Day(s)	D-D	Cat had Frontline Plus Spot-on Cat applied on 13 Nov 2019. Fur loss and skin irritation from the same day - nothing further.

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ED_005739D_00014391-00222

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
20-Nov-2019	UAE; 19UK003859; -; United Kingdom	**Species:** Canine **Breed:** Bichon Frise **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 5 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	01-Nov-2019	3 Day(s)	D-C	7 year old 5 kg female Bichon Frise dog was treated with Frontline Spot on Dog 10% w/v Spot on Solution on 29 Oct 2019. Dog was treated for first time in several years. Symptoms started on 1 Nov 2019 with swelling and eventual blistering of the skin. Dog suffered shaking and diarrhoea. Dog seen by owners vet, but nothing prescribed. Nothing further.
20-Nov-2019	UAE; 19UK003864; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	Nov-2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOG (estimated as FRONTLINE PLUS SPOT ON DOG M, batch number and expiry date unknown), route and frequency unknown, administered by the dog's owner on five occasions and the owner reported that the product did not work. The owner would not be buying it again. Date of event added for submission purposes only.
20-Nov-2019	UAE; 19UK003869; Gloucestershire; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	31-Oct-2019	N/A	D-D	As reported by the retail outlet, Mitzi, a canine (signalment otherwise unknown) was administered FRONTLINE SPOT ON DOG M (batch S21704BL expiry OCT 2021, details unknown) by the animal owner at a dose of 1 dose on 17 OCT 2019 for an unknown indication. The animal owner reported to the retail outlet that they always use FRONTLINE. Two weeks after applying it, their dog was scratching and so they waited and applied another pipette two weeks later. Their dog has not stopped scratching and is covered in fleas.
25-Nov-2019	UAE; 19UK003905; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown, details unknown) for an unknown indication. The animal owner reports that they bought the product as they usually do, but this time it hasn't seemed to have worked. The animal owner adds that they know that this product usually works well as they have used it many times before with no problems. This time it hasn't solved the problem. Start date for submission purposes only.
26-Nov-2019	UAE; 19UK003912; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other	Sep-2019	Sep-2019*	N/A	D-D	As reported by the animal owner, an 8 month old feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) for 2 months for an unknown indication. The cat still has fleas and the owner wonders if there is anything stronger.

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ED_005739D_00014391-00223

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** 8.00 Month(s) **Weight:** Unknown				products **Route:** unknown **Was the product used ok?:** Unknown to Company					
26-Nov-2019	UAE; 19UK003921; Berkshire; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Treatment / vaccination program not respected)	N/A	2019*	N/A	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown, details unknown) at a dose of 2 pipettes in a week, by the animal owner for an unknown indication. The animal owner reports that they returned the product as it doesn't seem to work. The animal owner has used other brands with some success but purchased the FRONTLINE PLUS spot on flea and tick treatment as it seemed to be a reputable brand. After using two pipettes in a week the fleas were unaffected and in fact seemed to be thriving . This resulted in a costly trip to the vet, after already spending a significant amount on the treatment. The animal owner would like a refund as nowhere does it say in the details that some dogs may be resistant to the treatment. Start date added for submission purposes only.
27-Nov-2019	UAE; 19UK003924; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 2.27 Year(s) **Weight:** 3.2 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	27-Oct-2019	29-Oct-2019	2 Day(s)	D-C	7 cats treated with Frontline Plus Spot-on Cat on 27 Oct 2019. 2 cats have had a suspected adverse reaction recorded in this case and lack of efficacy. The other 5 cats have a report of lack of efficacy in linked case UK-VMD-9758/19. Reporter states they bought this product to treat seven cats for flea infestation. The product has been completely ineffective and has caused one of my male cats to have a severe allergic reaction where he's come up in boils and another of my male cats a milder allergic reaction. I am very unhappy about this and concerned for the wellbeing of my cats. Loss of fur from constant grooming due to itchy allergic reaction. Treatment has been completely unresponsive in ridding any of my cats from fleas.
27-Nov-2019	UAE; 19UK003925; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	5	5	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	27-Oct-2019	29-Oct-2019	2 Day(s)	D-D	7 cats treated with Frontline Plus Spot-on Cat on 27 Oct 2019. 2 cats have had a suspected adverse reaction recorded in this case and lack of efficacy recorded in linked case UK-VMD-9664/19. The other 5 cats have a report of lack of efficacy recorded in this case . Reporter states they bought this product to treat seven cats for flea infestation. The product has been completely ineffective . Treatment has been completely unresponsive in riding any of my cats from fleas.
27-Nov-2019	UAE; 19UK003937; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON	N/A	25-Nov-2019	0 Day(s)	D-D	As reported by the animal owner, a male feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) by the animal owner 48 hours ago (25 NOV 2019) for an unknown indication. The animal owner reports that they have

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ED_005739D_00014391-00224

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					combed him today and found 2 alive fleas on him. They have been treating the animal for fleas for the past week with shampoo, flea spray and have sprayed the whole house. The animal owner is finding the live fleas all over him and have combed him a few times today, finding 2 to 4 live fleas every time. The animal owner reports that the FRONTLINE does not seem to have worked.
27-Nov-2019	UAE; 19UK003938; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	Nov-2019*	N/A	D-D	As reported by the animal owner, a female feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner over two weeks ago (NOV 2019) for an unknown indication. The animal owner is still combing live fleas out of her daily. They are also vacuuming and spraying the house every couple of days and have washed all the bedding at least twice on 90 degrees C.
29-Nov-2019	UAE; 19UK003950; -; United Kingdom	**Species:** Canine **Breed:** Bulldog **Sex:** M **Sex qualifier:** - **Age:** 9.00 Month(s) **Weight:** 20 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)	N/A	26-Oct-2019	N/A	D-D	9 month old 20 kg male Bulldog was treated with Frontline Plus Spot-on Dog S on 26 Oct 2019. Skin reaction, went red soon after applying (within 6 hours) followed by scabbing and hair loss. Clinical signs ongoing - nothing further.
28-Nov-2019	UAE; 19UK003952; Cumbria; United Kingdom	**Species:** Canine **Breed:** Cairn Terrier **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 9.5 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Oct-2019*	Oct-2019*	0 Day(s)	D-D	As reported by the animal owner, a Cairn Terrier canine weighing 9.5 kg (signalment otherwise unknown) was given FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG S, batch number S62709AW expiry date SEP 2021) via an unknown route by the animal owner for an unknown indication, in OCT 2019. The animal owner reports that they applied the product as instructed, unfortunately there was not much success as the fleas kept appearing. The animal owner reapplied the product on 22 NOV 2019 but again fleas were still present. Only 2 or 3 seemed to be adults and there were a large number of smaller ones. The animal owner intends to give their dog an insecticidal bath today as it does not seem very practical to put up with the problem until they can safely reapply FRONTLINE PLUS, as they don't think it has had much effect. Start date for submission purposes only.
02-Dec-2019	UAE; 19UK003975; -; United Kingdom	**Species:** Feline **Breed:** Feline Other **Sex:** F **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** Advantage 250	11-Nov-2019	11-Nov-2019	N/A	D-B	On 11 Nov the owner either administered half a pipette of Advantage for large dogs 10-25kg to the cat, or she administered this to the dog but the cat licked some of the product off the dog. Within 24 hours the cat presented at the vet with seizures and muscle tremors. The cat was admitted to the hospital and given diazepam. The muscle tremors continued so the cat was treated

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ED_005739D_00014391-00225

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 7.00 Year(s) **Weight:** 4 kg				Spot-on Solution for Dogs; Intralipid (human); **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					with intralipid on 12 Nov. In the evening on 12 Nov the muscle tremors had improved. In the morning on 13 Nov there was no more evidence of muscle tremors, or any further seizures, so the cat was discharged. No other products were used concurrently. It is unknown whether the cat has been treated with Advantage before. FUP received on 18th November 2019: On 15 Nov the cat had a routine re-examination at the vet. The cat was found to be much improved and there were no more muscle tremors. The was still some slight twitching and incoordination and possibly some slight weakness on the right side. The owner thinks it is unlikely that she applied the Advantage for large dogs directly to the cat and thinks the most likely scenario is that she applied Frontline to the cat and the Advantage to the dog and then the cat may have licked the dog and had some oral uptake of Advantage.
01-Dec-2019	UAE; 19UK003983; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	Nov-2019*	0 Day(s)	D-D	As reported by the animal owner, a puppy (signalment otherwise unknown) was given FRONTLINE SPRAY (batch and expiry unknown) by the animal owner as a parasiticide (no further information available). The animal owner reports that the product hasn't worked and the puppy still has fleas. Start date for submission purposes only.
01-Dec-2019	UAE; 19UK003984; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	24-Nov-2019*	8 Day(s)	D-D	As reported by the animal owner, approximately two felines including one female (signalments otherwise unknown), were given FRONTLINE PLUS SPOT ON CAT (batch number S41113 and expiry date AUG 2021) on 16 NOV 2019 topically to an unknown site by the animal owner as a parasiticide. The animal owner reports that they applied the product carefully and directly to their cats' skin. Last week (NOV 2019) the animal owner realised that one of their cats started to itch and her hair has gone. The animal owner saw a big flea and lots of flea eggs on their other cat's skin. They are indoor cats and never go out. This case is classified as both 'SLEE' and 'Adverse Reaction' but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse Reaction', has been transmitted.
01-Dec-2019	UAE; 19UK003985; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Jul-2019*	Jul-2019*	0 Day(s)	D-C	As reported by the animal owner, a male canine (signalment otherwise unknown) was given FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch number R20507AR expiry date FEB 2020) via an unknown route by the animal owner in JUL 2019 (no further details available). The animal owner reports that she ended up with a very poorly dog, they didn't need to go to the vets but all the same he was extremely unwell, upset tummy, really lethargic, and unwilling to go out for a walk and just laid down on his bed. The animal owner has always used our products with their other dogs whilst they were alive (see linked case GBR-BIAHPV1P-19UK003986), they have never experienced anything like this, and they were that frightened that they didn't use the product on their other dog. The outcome is unknown. Start date for submission purposes only.

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ED_005739D_00014391-00226

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
01-Dec-2019	UAE; 19UK003986; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	2	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	01-Dec-2019*	0 Day(s)	D-A	As reported by the animal owner, a approximately 2 canines (signalment otherwise unknown) were given FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) by the animal owner (no further information available.) The animal owner reports that they always used our products on their other dogs while they were alive. Linked to case GBR-BIAHPV1P-19UK003989. Start date for submission purposes only.
02-Dec-2019	UAE; 19UK004001; -; United Kingdom	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 3 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	N/A	23-Nov-2019	N/A	D-D	As reported by the animal owner, Maizy a 4 year old female neutered Domestic Short Hair feline, weighing 3 kg and in good condition, was administered FRONTLINE SPOT ON CAT (batch S21509BX expiry SEP 2021) topically to an unknown site, by the animal owner, at a dose of 1 pipette per month for preventative care. The animal owner applies FRONTLINE SPOT ON every 4 weeks all year round, and gave one after three weeks as they saw fleas. The animal owner has lived in the house for 22 years and has always used FRONTLINE SPOT ON. On 23 NOV 2019 the animal owner saw a flea on one cat. The animal owner sprayed the house yesterday and has washed all bedding. The last four treatment dates are 23 NOV 2019, 04 NOV 2019, 04 OCT 2019 and 04 SEP 2019. The animal owner is happy to continue as they are doing and persevere.
03-Dec-2019	UAE; 19UK004004; -; United Kingdom	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** - **Age:** 5.00 Year(s) **Weight:** 40 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	Jun-2019*	Jul-2019*	N/A	D-C	As reported by the animal owner, Buck, a 5 year old male intact canine (signalment otherwise unknown) weighing 40 kg and in good condition, was administered FRONTLINE SPOT ON (assumed FRONTLINE SPOT ON DOG L, batch and expiry unknown, details unknown) topically to the back of the neck between the shoulders, by the animal owner, at a dose of 1 pipette, in JUN 2019 as they saw fleas. About one month after this a scab appeared. The animal owner cut this off with scissors. It then reappeared and the animal owner cut it off again. Now the animal has a huge gash where the scab was. The animal has not been to the vets. The animal is not good at the vets and so the animal owner does not want to go. UPDATE 20 DEC 2019: The animal owner reported that they applied FRONTLINE to his dog between the shoulder blades in JUN 2019. A 2 inch scab formed at the application site which they left for some time, but it wasn't going anywhere so they used scissors to remove, they did not cut the skin, just the fur and the scab away. After the first time removing the scab, a further scab formed and again they used scissors to remove the scab and the fur. They were not traumatizing the skin in any way. They removed the scab because it was not going anyway, it was like a growth. The vet used clippers to remove the scab again and to shorten the dog's fur around the area. An ointment, which the animal owner purchased and does not know the name of, is being applied to the wound and sore skin area. The animal owner feels this wound scab is simply not going to go away. The dog is a long coat German Shepherd Dog so his fur gets caught up in the wound and scab when healing. The animal owner has not bathed or cleaned the irritated skin at any point, just used the ointment they purchased. On 23 DEC 2019 the attending vet reported that the animal came in on 15 DEC 2019 and they were unable to examine

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ED_005739D_00014391-00227

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											the animal as he was very aggressive, and the animal owner could not handle him either. The animal owner
03-Dec-2019	UAE; 19UK004010; Suffolk; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** Puppy **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Indication not indicated / recommended)	26-Nov-2019*	03-Dec-2019	1 Week(s)	D-D	As reported by the attending vet, a puppy (signalment otherwise unknown), was treated with FRONTLINE SPRAY (batch number and expiry date unknown), applied topically by the attending vet a week previous to the date of the report (date of application estimated as 26 NOV 2019), as the puppy had cheyletiella, that had been confirmed via tape strips. On 03 DEC 2019 the vet reported that the dog was still quite itchy.
04-Dec-2019	UAE; 19UK004016; -; United Kingdom	**Species:** Canine **Breed:** Great Dane **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 65 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	N/A	D-D	As reported by the animal owner, a Great Dane canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG XL) (Batch and expiry unknown) (details unknown) by the animal owner for an unknown indication. The animal owner reports that after using this product for 40 years they are very dissatisfied and disappointed this time round after spending money to do their Great Dane. After a week of applying the product as they have done for numerous years they were upset to see that the animal still has live fleas. All the house has been treated (product unknown) and one carpet that the animal owner had has been renewed. The animal owner states that it isn't a reinfestation as the fleas have never gone. The animal owner is very disappointed as they now have to go to the vets and spend another amount of cash as FRONTLINE has not worked. The animal owner now feels that the fleas have become immune to it. Start date added for submission purposes only. This case is linked to GBR-BIAHPV1P-19UK004017 and GBR-BIAHPV1P-19UK004018. UPDATE 06 JAN 2020: The animal, Otis, is a 5 year old male Great Dane canine weighing 65 kg. The animal owner adds that they treat the animal monthly all year round and they started using the product for the current flea issue in November. They first noticed fleas on their pet on 31 OCT 2019 and apply the product to the back of the neck under the fur. People in the home are being bitten, the animal spends time indoors only and all animals in the household and in contact animals have been treated with a flea product. The animal owner is seeing many fleas - 5 or more at the same time - the animal is bathed or goes swimming more than once a week and they have treated the home with an environmental flea treatment (PDSA home spray), washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pet can access.
04-Dec-2019	UAE; 19UK004017; -; United Kingdom	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s)	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous	Nov-2019*	Nov-2019*	N/A	D-D	As reported by the animal owner, a small crossbreed canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG S) (Batch and expiry unknown) (details unknown) by the animal owner for an unknown indication. The animal owner reports that after using this product for 40 years they are very dissatisfied and disappointed this time round after spending money to do their small crossbreed dog. After a week of applying the product as they have done for numerous

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ED_005739D_00014391-00228

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 9 kg				**Was the product used ok?:** Unknown to Company					years they were upset to see that the animal still has live fleas. All the house has been treated (product unknown) and one carpet that the animal owner had has been renewed. The animal owner states that it isn't a reinfestation as the fleas have never gone. The animal owner is very disappointed as they now have to go to the vets and spend another amount of cash as FRONTLINE has not worked. The animal owner now feels that the fleas have become immune to it. Start date added for submission purposes only. This case is linked to GBR-BIAHPV1P-19UK004016 and GBR-BIAHPV1P-19UK004018. UPDATE 06 JAN 2020: The animal, Sindy, is a 1 year old female mixbreed canine weighing 9 kg. The animal owner adds that they treat the animal monthly all year round and they started using the product for the current flea issue in November. They first noticed fleas on their pet on 31 OCT 2019 and apply the product to the back of the neck under the fur. People in the home are being bitten, the animal spends time indoors only and all animals in the household and in contact animals have been treated with a flea product. The animal owner is seeing many fleas - 5 or more at the same time - the animal is bathed or goes swimming more than once a week and they have treated the home with an environmental flea treatment (PDSA home spray), washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pet can access.
04-Dec-2019	UAE; 19UK004018; -; United Kingdom	**Species:** Feline **Breed:** Feline crossbred **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 7 kg	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	Nov-2019*	Nov-2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT) (Batch and expiry unknown) (details unknown) by the animal owner for an unknown indication. The animal owner reports that after using this product for 40 years they are very dissatisfied and disappointed this time round after spending money to do their cat. After a week of applying the product as they have done for numerous years they were upset to see that the animal still has live fleas. All the house has been treated (product unknown) and one carpet that the animal owner had has been renewed. The animal owner states that it isn't a reinfestation as the fleas have never gone. The animal owner is very disappointed as they now have to go to the vets and spend another amount of cash as FRONTLINE has not worked. The animal owner now feels that the fleas have become immune to it. Start date added for submission purposes only. This case is linked to GBR-BIAHPV1P-19UK004016 and GBR-BIAHPV1P-19UK004017. UPDATE 06 JAN 2020: The animal, Eboney, is a 1 year old male mix breed feline weighing 7 kg. The animal owner adds that they treat the animal monthly all year round and they started using the product for the current flea issue in November. They first noticed fleas on their pet on 31 OCT 2019 and apply the product to the back of the neck under the fur. People in the home are being bitten, the animal spends time indoors only and all animals in the household and in contact animals have been treated with a flea product. The animal owner is seeing many fleas - 5 or more at the same time - the animal is bathed or goes swimming more than once a week and they have treated the home with an environmental flea treatment (PDSA home spray), washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pet can access.

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ED_005739D_00014391-00229

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
05-Dec-2019	UAE; 19UK004030; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, three felines (signalment otherwise unknown) were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON CAT) (batch and expiry unknown) (details unknown) by the animal owner for an unknown indication. The animal owner reports that they recently bought FRONTLINE PLUS as they couldn't get Advantage at the time, which is what they normally use as they work out cheaper. They used to use FRONTLINE all the time but it seemed to become ineffective. The animal owner is really disappointed that this product is still ineffective on all three of their cats and they have had to spend out again to get Advantage to sort out the problem . Start date added for submission purposes only.
07-Dec-2019	UAE; 19UK004055; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male feline (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) topically to an unknown site by the animal owner for an unknown indication. The animal owner reports that they always use FRONTLINE PLUS on their cat once a month and he is fine putting it on and for an hour or so afterwards but then he starts scratching the area where they have put the FRONTLINE PLUS on. Start date for submission purposes only.
08-Dec-2019	UAE; 19UK004059; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male canine (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M) (batch and expiry unknown) (details unknown) for an unknown indication. The animal owner bought the product and is not happy with it as it doesn't work. They have now had to take their dog to the vets because he has fleas, even though he was on his second course. He was covered in fleas. The animal owner had to buy a tablet from the vet to deal with the fleas. Start date added for submission purposes only.
09-Dec-2019	UAE; 19UK004064; Cheshire; United Kingdom	**Species:** Canine **Breed:** Bulldog **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 11.3 kg	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	23-Oct-2019	23-Oct-2019*	0 Day(s)	D-C	As reported by the distributor, Sully an intact male British Bulldog canine born on 23 JUL 2019, weighing 11.3 kg and in unknown condition was given FRONTLINE SPOT ON DOG S (batch and expiry unknown) on 23 OCT 2019 topically to an unknown site by the animal owner as a flea and worm treatment. The animal owner brought the dog to the distributor's store to get FRONTLINE, they were told the best one they sell is FRONTLINE. The animal owner used the product on the dog, the dog has been acting up and the dog's chest was raw the next day. The animal owner took the dog to the vets. The attending vet examined the dog on 24 OCT 2019 and found that mucous membranes were pink and capillary refill time was less than 2 seconds. The product had been applied yesterday night, on 24 OCT 2019 there was a rash on the skin of the neck, tiny lumps. The attending vet reported it looked like an allergy reaction. The dog had been quiet at home but was bright in

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ED_005739D_00014391-00230

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											the consult, was DUDE (defecating, urinating, drinking, eating) and had no breathing difficulties. The dog was given a steroid injection (Dexadreson) and dispensed Prokolin. The dog had had loose stools for the last 7 days (pre-existing), no diarrhoea. On 26 OCT 2019 the animal owner took the dog to another vet. The vet reported that the dog was now bleeding, there were two scratching areas on the sides of the neck and a sore area under the screw tail. The attending vet dispensed Noroclav and Clorexyderm.
09-Dec-2019	UAE; 19UK004067; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	28-Nov-2019*	Nov-2019*	approximately 6 weeks	D-D	As reported by the animal owner, two canines (signalment otherwise unknown) were given FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown) 6 weeks ago (estimated 28 NOV 2019) via an unknown route by the animal owner (no further details available). The animal owner reports that one dog is OK but the other one is scratching, however this is not at the application site. Start date for submission purposes only.
10-Dec-2019	UAE; 19UK004071; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	28-Oct-2019	28-Oct-2019	0 Day(s)	D-C	Dog was treated with Frontline Plus Spot-on Dog L on 28 Oct 2019. From the same day the dog developed blood spots on its body and inside the mouth. Vet confirmed it could be due to the frontline plus treatment, dog was given vitamin k1 and steroids. No further information.
10-Dec-2019	UAE; 19UK004082; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	10-Dec-2019*	8 Week(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOG (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, route and frequency unknown, administered by unknown, 8 weeks ago or less (date of administration estimated as 10 OCT 2019) and the owner reported that it did not resolve the problem, they were still seeing many fleas 5 or more at the same time. The owner confirmed that the dog never went swimming and the people in the home were not being bitten. The owner had treated the home with an insecticidal household flea product, had washed the pets bedding and had vacuumed regularly.
16-Dec-2019	UAE; 19UK004115; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	1	1	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown	N/A	15-Dec-2019	2 Day(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M), route, dose and frequency unknown, administered by unknown, on 13 DEC 2019 and the owner reported that on 15 DEC 2019 (2 days later) the owner found 5 fleas on the dog.

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ED_005739D_00014391-00231

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				**Was the product used ok?:** Unknown to Company					
18-Dec-2019	UAE; 19UK004130; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, two felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT) (batch and expiry unknown) (details unknown) by the animal owner for and unknown indication. The animal owner reports that they have used the product for years and it has been fine, killed all the fleas. However this last two times that they have used it on their two cats if has not killed any, and they have been bitten to hell. They have washed and sprayed everywhere and to no avail. It has not got rid of them. This time of year as well is surprising as it is usually August that is the worst. Date of event added for submission purposes only.
06-Dec-2019	UAE; 19UK004147; -; United Kingdom	**Species:** Feline **Breed:** Feline various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	06-Dec-2019	approximately 2 Week(s)	D-D	As reported by the animal owner, their 3 cats, 2 of which were Ragdoll cats (signalment otherwise unknown) were treated with FRONTLINE (assumed to be FRONTLINE SPOT ON CAT) batch number, expiry date, and further details unknown, date of administration estimated as 22 NOV 2019, as the cats had fleas. On 06 DEC 2019 (2 weeks later) the owner reported that the cats still had fleas and that the product was not working. The owner reported that they were clean people and mainly had wood floors.
22-Dec-2019	UAE; 19UK004153; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Sep-2019*	Dec-2019*	0 Day(s)	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was given FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON CAT, batch and expiry unknown) by the animal owner starting approximately 3 months ago (no further details available). The animal owner reports that they have treated their dog (see linked GBR-BIAHPV1P-19UK004154) and cat for 3 months with FRONTLINE PLUS as they had fleas, and they still have them after 3 months of treatment. The animal owner reports that usually after the first dose they have gone, they have washed the bedding and sprayed around the house too (product unknown). Start date for submission purposes only.
22-Dec-2019	UAE; 19UK004154; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Sep-2019*	Dec-2019*	0 Day(s)	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was given FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown) by the animal owner starting approximately 3 months ago (no further details available). The animal owner reports that they have treated their dog and cat (see linked case GBR-BAIAPV1P-19UK004153) for 3 months with FRONTLINE PLUS as they had fleas, and they still have them after 3 months of treatment. The animal owner reports that usually after the first dose they have gone, they have washed the bedding and sprayed around the house too (product unknown). Start date for submission purposes only.
23-Dec-2019	UAE; 19UK004158;	**Species:** Feline **Breed:** Feline	1	1	0	**Product used:** FIPRONIL SPOT	21-Dec-2019	21-Dec-2019	0 Day(s)	D-D	As reported by the animal owner, a female feline in good condition (signalment otherwise unknown) was administered FRONTLINE

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ED_005739D_00014391-00232

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; United Kingdom	(unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					SPOT ON CAT (batch and expiry unknown) (details unknown) topically by the animal owner, on 21 DEC 2019 as preventative care. The animal owner reports that they purchased the product two days ago and have put the treatment on their cat. Today they can still see fleas (reported as 2) on the stomach area. They are not impressed as they usually buy single treatments, Advantage from the vets, and they kill them very fast. The animal owner does not know whether they should put another one on or get one from the vet.
24-Dec-2019	UAE; 19UK004161; -; United Kingdom	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 5 kg*	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	21-Aug-2019	24-Dec-2019*	19 Day(s)	D-D	As reported by the animal owner, a female domestic Shorthair feline aged 6 years and weighing approximately 6 kg (signalment otherwise unknown), was treated with FRONTLINE SPOT ON CAT (batch number: S21204AW and expiry date AUG 2021) on 05 DEC 2019 administered by the cat's owner to the back of the neck for many years, according to the instructions. The owner reported on 24 DEC 2019 that the product was now not as effective as the last few applications did not appear to be getting rid of the fleas. They had found a flea on a few occasions during the last few applications, within just a week of application they had found a living flea. They had not applied another dose because it was too soon from the previous application. The owner was wondering if the product had changed in its composition in any way to account for this. The animal owner reports that they use FRONTLINE regularly, approximately every 4 to 5 weeks. They use it all year round and more frequently in warmer weather in accordance with the directions. The last four dates they applied FRONTLINE are 21 AUG 2019, 25 SEP 2019, 09 NOV 2019 and 05 DEC 2019. Regarding the current flea issue, the animal owner first noticed a flea after applying the NOV dose and thought it was a one off . Therafter, they noticed a flea a few weeks later, which was when they decided to apply FRONTLINE slightly sooner than they would have otherwise. They saw a flea on another two or three occasions after applying the DEC dose. The cat is mainly an indoor cat and only goes outside for toilet purposes. The animal owner usually only sees one flea at a time. The cat doesn't wear a collar, get bathed or go swimming. The animal owner has lived at the property for 30 years. The animal owner hasn't used any additional spray as they don't which are effective. They regularly vacuum the bedding and all communal areas.
25-Dec-2019	UAE; 19UK004177; -; United Kingdom	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	N/A	2019*	N/A	D-C	As reported by the animal owner, a male canine of unknown signalment was treated with FRONTLINE PLUS (assumed M), on an unknown date (further details unknown). After the second application the dog had a red sore (assumed at the application site), which the owner believed to be a chemical burn, and now he has a big scab there. The owner commented that the product has caused the dog to have a scab where they put the spot on flea product and has caused a bad allergic reaction (assumed also at the application site). No further information was provided. Start date added for submission purposes only.
14-Dec-2019	UAE; 19UK004182; -; United Kingdom	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products**	N/A	2019*	N/A	D-D	As reported by the animal owner, a male feline (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch and expiry unknown) (details unknown) at a dose of 1 dose monthly for an unkown indication. The animal owner reports

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ED_005739D_00014391-00233

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				**used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					that the cat came home with fleas after being in a cattery, despite using FRONTLINE SPOT ON every month. The animal was treated 36 hours ago and they are still seeing fleas. Start date added for submission purposes only.
27-Dec-2019	UAE; 19UK004183; -; United Kingdom	**Species:** Canine **Breed:** Schnauzer (Miniature) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Treatment / vaccination program not respected)	22-Dec-2019	22-Dec-2019	N/A	D-D	As reported by the animal owner via Social Media, two Miniature Schnauzer canines weighing less than 10 kg (signalment otherwise unknown) were administered FRONTLINE SPOT ON DOG (assumed FRONTLINE SPOT ON DOG S) (batch and expiry unknown) (details unknown) 5 days ago (22 DEC 2019) after noticing an infestation. The animal owner bathed them, washed all the bedding and toys on a boil wash and made sure to spray the carpets and soft furnishings with flea powder too. On 27 DEC 2019 the animal owner noticed one flea on one of the dogs and so the animal owner bathed them yet again, and used the third and final pipette in the packet, using half of the pipette on each (half the specified dose). The animal owner is now concerned about overdose as they did not realise that the product was still effective after bathing. Each dog has technically had 1.5 of the specified dose within a 5 day period.
30-Dec-2019	UAE; 19UK004188; -; United Kingdom	**Species:** Canine **Breed:** Canine various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Aug-2019*	01-Dec-2019*	N/A	D-D	As reported by the animal owner, three Pug canines and one Boxer canine (signalment otherwise unknown) were given FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown) for the last four months (assumed starting AUG 2019) by the animal owner as a parasiticide (no further details available). The animal owner reports that the dogs still have fleas. They do not come into contact with other dogs. The animal owner feels the product is not working and they expected better results. Start date for submission purposes only.
20-Nov-2019	UAE; 19US030527; NC; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 68 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Oct-2019	20-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the pet owner reported the following event for Gotti, an 11 year old, 68 lb, neutered male Pit Bull. 17 May 2019: Dog received one dose of FRONTLINE PLUS DOG 45-88 LBS (S62408AX) (FL) topically between the shoulder blades. The pet owner reported seeing fleas prior to the use of the product. This is the first treatment of the season. Fleas have been seen both in the home and on the pet. The dog is walked outside daily and the owner finds about 12 fleas at a time when checking. The FL has been used in the past with no incident. No further medical information expected. UPDATE 13 Jun 2019: Case changed to an inquiry due to preexisting fleas and only one dose administered. UPDATE 20 Nov 2019: The owner reported monthly use of the product since the initial May dosing. On 19 Oct 2019, the most recent dose was applied. The owner continued to see live fleas on the pet during this time frame. The dog was bathed in Lavendar Palm Olive on two unknown dates during the summer of 2019. On 15 Nov 2019*, the owner applied an unknown flea collar and has not seen any fleas. No further medical information expected.

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ED_005739D_00014391-00234

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
21-Nov-2019	UAE; 19US033621; IN; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** X **Sex qualifier:** Mixed **Age:** 5.00 Year(s) **Weight:** 50 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Jun-2019	09-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 12 Jun 2019, the owner reported the following event for 2 Pit Bulls, weighing 50 pounds each,1 intact male and 1 female, around 5 years of age. 9 Jun 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S62118AL) was applied topically in between the pet's shoulder blades by the owner. 10 Jun 2019: A moderate amount of fleas were seen on the male dog, the female does not have any fleas seen. The dogs are indoor mostly and access to a fenced in yard for potty breaks and recreation. No wildlife or stray animals a noticed in the area and owner is treating the yard and the home. No indoor fleas seen. This is the first treatment of FRONTLINE PLUS and fleas were seen for about a week prior to treatment. No further medical information expected. UPDATE 24 Jun 2019: Case changed to an inquiry due to preexisting fleas and only one dose administered. UPDATE 21 Nov 2019: Owner used the remaining FRONTLINE PLUS that she started using on 9 Jun 2019 over the months of Jul 2019* and Aug 2019*. She is still seeing fleas to this day. No further information is expected.
21-Oct-2019	UAE; 19US039496; CA; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** X **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 14 - 18 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	26-Jun-2019*	08-Jul-2019	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, a pet owner reported the following event for 3 Shih Tzu altered canines of mixed sex, ranging from 2 to 4 years old and 14 to 18 pounds. 26 Jun 2019*: The dogs received 1 application of FRONTLINE PLUS 5-22 LBS (Lot Unknown) topically between the shoulder blades for the first time. The pet owner was noticing approximately 3 live fleas on each of the dogs prior to FRONTLINE application. 8 Jul 2019: The pet owner noticed several live fleas on the dogs. The pet owner is not noticing any fleas in the house. The yard is fenced in and there is no grass, trees, or bushes on the property. The pet owner wants to bathe the dogs with a flea shampoo. The pet owner usually applies Revolution to the dogs during the summer months. No further medical information expected. UPDATE 16 July 2019: The case changed to inquiry based off treatment program not respected. UPDATE 21 Oct 2019: 26 Jul 2019: A dose was applied to the pets. 26 Aug 2019: A dose was applied to the pets. 26 Sep 2019: A dose was applied to the pets. The owner has continued to see a large number of fleas throughout this time. No further medical information expected.
01-Oct-2019	UAE; 19US041232; TX; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Jun-2019	15-Jul-2019	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019 an animal owner reported the following event in a feline. All other signalment unknown. 15 Jun 2019: FRONTLINE PLUS CATS (lot S40901AW) was applied between the shoulder blades for the first time. There were fleas at time of administration. 15 Jul 2019: FRONTLINE PLUS applied to feline. The animal owner is still seeing fleas. No other pets in the household. Feline is indoor only. Caller not receptive. No further information provided nor expected. UPDATE 26 Jul 2019: Case updated to inquiry due to treatment program not respected. UPDATE 30 Sep 2019: The pet owner called and stated that another dose of FRONTLINE was applied on 15 Aug 2019 and she is still seeing fleas. It is unknown how many fleas she is seeing .

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ED_005739D_00014391-00235

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											No further information expected.
24-Oct-2019	UAE; 19US042473; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	6	6	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Jul-2019*	23-Oct-2019*	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 19 Jul 2019 the pet owner reported the following event for six unknown felines. All other signalments are unknown. *4 Jul 2019: The owner applied 1 vial of FRONTLINE PLUS CATS (UNKNOWN) to the skin between the shoulder blades for the first time because the owner noticed an unknown amount of fleas. *5 Jul 2019: The owner continued to notice about 6-24 fleas on the cats twice daily. 19 Jul 2019: The owner bathed the cats in dawn dish soap. There are no other pets in the home. The cats are all indoor only. The owner is not noticing any indoor flea activity. No further medical information expected. UPDATE 2 AUG 2019: Case updated to Inquiry due to treatment program not respected. UPDATE 24 Oct 2019: Per clinic phone call, the owner is still seeing fleas. 23 Oct 2019: Owner came into clinic and the doctor saw many fleas. Cats were all treated with Capstar. Owner has been giving FRONTLINE every month since Jul 2019*. No further information is expected.
07-Nov-2019	UAE; 19US047151; WA; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 25 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	16-Jul-2019	16-Jul-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On the 7 Aug 2019, a pet owner reported the following event for Popsicle, a 25 pound, 5 year old, spayed female, Small Crossbred. 16 Jul 2019: The dog was started on monthly FRONTLINE PLUS DOG 23-44 LBS (S61009AL), with 1 dose applied topically, between the shoulder blades. The pet owner was already seeing a large amount of fleas on the dog. The owner switched from a flea powder that she felt was not working on her dog. The dog is the only pet in the home. The dog is indoor/outdoor. She has access to 7 acres of land with lots of grass, bushes and trees. The dog spends about 6 hours outside and the remainder of the time indoor. The owner was not seeing fleas inside of the home, only on the dog. 23 Jul 2019: The pet owner was still seeing a large amount of fleas on the dog so she applied another dose based on the recommendation from the veterinarian. 6 Aug 2019: The pet owner bathed the dog and is still seeing a large amount of flea on the dog but not inside of the home. The issue is ongoing. No further information expected. UPDATE 20 AUG 2019: Case updated to Inquiry due to treatment program not respected. UPDATE 7 Nov 2019: Per the pet owner, FRONTLINE PLUS DOG 23-44 LBS was applied in the manner previously described on 20 Sep 2019* and 20 Oct 2019*. Presently, the dog continues to pick up fleas. It's unknown if fleas were present when the subsequent vials were applied. There was a cat in the home temporarily from at least Jul 2019 to early Sep 2019. That cat was receiving an unknown topical flea/tick control product on the same dates as Popsicle. It's unknown if that cat had fleas. The cat has since moved out of the home with the reporter's daughter. No further medical information expected.
12-Nov-2019	UAE; 19US048204; CA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	07-Aug-2019	13-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 13 Aug 2019, a pet owner reported the following event for Newman, a 15 year old, 18 pound, male neutered Domestic Longhair. 7 Aug 2019: The owner applied 1 dose of FRONTLINE PLUS

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ED_005739D_00014391-00236

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: M **Sex qualifier:** Neutered **Age:** 15.00 Year(s) **Weight:** 18 lbs				12% SPOT ON **Other products used:** Capstar; flea shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					CATS (lot unknown, package unavailable) for the first time and the cat had fleas. The owner bathed the cat in a flea shampoo, gave Capstar and is spraying the house. 13 Aug 2019: The cat still has fleas. There are no other pets in the house, the cat is indoor only. No further medical information expected. UPDATE 26 Aug 2019: Case updated to inquiry due to treatment program not respected. UPDATE 12 Nov 2019: The pet owner applied product on 7 Sep 2019 and 7 Oct 2019 and is still seeing an unknown amount of fleas. No further medical information expected.
04-Nov-2019	UAE; 19US048843; CT; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Jul-2019	28-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 15 Aug 2019 a pet owner reported the following event for Precious, an 8 pound*, 9 year old, spayed female Domestic Shorthair. 22 Jul 2019*: Owner started seeing an unknown amount of fleas on the cat. 28 Jul 2019: Owner applied FRONTLINE PLUS CATS (S40606AW) to the skin on the animal's neck for the first time. The owner has continued to flea comb the cat 2-3 times a day a day since application and is finding 10 live fleas each time. The owner has seen no fleas in the home and she is spraying the home and the screened in porch with Zodiac house spray daily. Precious lives indoors and goes out onto the screened in porch on occasion. There are no other animals in the home. The cat is not bathed. No further medical information expected. UPDATE 29 AUG 2019: Case updated to Inquiry due to treatment program not respected. UPDATE 04 Nov 2019: per converstaion iwth animal owner the following was reported. 28 Aug 2019 and 28 Sep 2019: The animal owner applied FRONTLINE PLUS. Fleas were seen on feline at time of administration. 15 Oct 2019: The animal owner combed with diluted Dawn dish soap as the feline still had fleas. 30 Oct 2019: The feline continued to have fleas. A Seresto collar applied. 02 Nov 2019: No fleas seen on feline. No further information provided. Changed case to adverse event as 2 additonal doses were adminsitered.
09-Oct-2019	UAE; 19US050161; NY; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** - **Age:** 8.00 Year(s) **Weight:** 9 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn Dish Soap; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Aug-2019*	09-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 13 Aug 2019, the pet owner reported the following event for Desaray, a 8 year old, 9 pound*, intact male, Chihuahua Terrier Mix. 31 Jul 2019*: Fleas were noticed prior to dose of FRONTLINE. 1 Aug 2019*: The animal got a Dawn Dish Soap bath. 2 Aug 2019: The patient got a dose of FRONTLINE PLUS DOG 5-22 LBS(S61902AL). This was the first dose of the year. The owner purchased a 3 pack this past purchase, and the animal has used FRONTLINE in a prior year, but exact dates are unknown. It was applied between the shoulder blades. 3 Aug 2019*: The owner still noticed fleas. The dog does go outside daily. The pet is showing no skin issues. There are no fleas in the home, and no fleas on the owner. Owner treated house with flea bomb after FRONTLINE dose was given. The patient's current condition is ongoing. There is a total of 2 canines and 4 felines in the household. The

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Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											owner reported a lack of efficacy for the other dog, case19US050156. She also reported a lack of efficacy for the cats, case 19US048356. No further medical information expected. UPDATE 26 AUG 2019: Case updated to Inquiry due to treatment program not respected. UPDATE 2 Sep 2019 - 2 Oct 2019: The owner applied FRONTLINE to the pet. 9 Oct 2019: As per the owner, she continues to see fleas on the pet. The pet owner switched to another unknown flea preventative. No further medical information expected.
08-Oct-2019	UAE; 19US051104; NY; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 15.000 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Jul-2019	26-Aug-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 26 Aug 2019, a pet owner reported the following event for baby, a 15 pound, 13 year old, spayed female, Domestic Longhair. 28 Jul 2019: The owner applied for the first time 1 dose of FRONTLINE PLUS CATS (S41004AW), topically between the shoulder blades. The pet owner was seeing a moderate amount of fleas on the cat. The cat is the only animal in the home. She is strictly indoors. The owner applies flea and tick seasonally and this was the first dose that was applied for this season. 24 Aug 2019: The most recent dose was applied to the cat. 26 Aug 2019: The pet owner is still seeing a moderate amount of fleas on her cat. The issue is ongoing. No further medical information expected. UPDATE 05 Sept 2019: Case changed to inquiry based off treatment program not respected. Product has not been used for a minimum of 90 days. UPDATE 8 Oct 2019: Per information received from the pet owner for Suspected Lack of Efficacy and now Suspected Adverse Event: 17 Sept 2019: The pet owner applied FRONTLINE PLUS CATS, for the third time. Unknown date: The pet owner was still seeing fleas on the cat. The cat was experiencing pruritus and was scratching. The cat presented to the veterinary clinic on an unknown date and was treated with prednisone tablets, Capstar and an unknown antibiotic injection. The veterinarian informed the pet owner that the cat had dry skin. Unknown date: The cat presented to a dermatologist and was treated with prednisone injection, antibiotic injection, Capstar and a Seresto collar. The cat is doing better, but has not completely recovered. No further medical information expected.
25-Nov-2019	UAE; 19US051291; OK; U.S.A	**Species:** Canine **Breed:** Pomeranian **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 12 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Aug-2019	26-Aug-2019*	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Aug 219, the owber reported the following event for Jack, a 12 pounds, 4 year old*, neutered male Pomeranian. 14 Aug 2019: The owner saw a moderate amount of fleas on Jack. 16 Aug 2019: One dose of FRONTLINE PLUS DOG 5-22 LBS (S61902AL), was applied topically in between the shoulder blades. 26 Aug 2019: The owner reports still seeing fleas. Jack is considered an indoor/outdoor dog that goes outside for occasional walks and potty breaks. There were a moderate amount of fleas seen prior to product use. There is 1 other dog in the home that is also on the same box of FRONTLINE does not have fleas. This was the pet's first dose of FRONTLINE. No further information at this time. UPDATE 06 Sept 2019: Case changed to inquiry based off treatment program not respected. Product has not been used for a minimum of 90 days.

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ED_005739D_00014391-00238

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											UPDATE 25 Nov 2019: 13 Sep 2019: The monthly dose was applied. 13 Oct 2019: The monthly dose was applied. 13 Nov 2019: The monthly dose was applied. The owner has seen a consistent number of fleas on the pet since Aug 2019. The other dog in the home is also treated with FRONTLINE PLUS DOG 5-22 LBS. Fleas are being see on this pet, see case USA-BIAHPV1P-19US068615. No further medical information expected.
13-Nov-2019	UAE; 19US051457; FL; U.S.A	**Species:** Canine **Breed:** Shar Pei **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Aug-2019	12-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On the 27 Aug 2019, a pet owner reported the following event for Sammie, a 15 pound, 11 year old, neutered male, Shar Pei and Terrier Mix 12 Aug 2019: The owner applied for the first time 1 dose of FRONTLINE PLUS DOG 5-22 LBS (S61902AL) topically between the shoulder blades. The owner was seeing a large amount of fleas on the dog and inside of the home since August prior to using the product. The dog is indoor/outdoor but he spends the majority of his time indoors. When the dog goes outside he has access to a fenced in backyard with grass and trees. There are no other animals in the home. 27 Aug 2019: The owner is still seeing a large amount of fleas in the home and on the dog. The issue is ongoing. No further medical information expected. UPDATE 9 Sep 2019: Case updated to Inquiry due to treatment program not respected. UPDATE: 13 Nov 2019: Per the owner: 12 Sep 2019: The owner applied 1 dose topically between the shoulder blades. The owner was seeing an unknown amount of fleas on the dog. 12 Oct 2019: The owner applied 1 dose topically between the shoulder blades. The owner was seeing an unknown amount of fleas on the dog. 12 Nov 2019: The owner is still seeing an unknown amount of fleas on the dog. No further medical information expected.
02-Oct-2019	UAE; 19US052185; NY; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jul-2019*	02-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 30 Aug 2019, the pet owner reported the following event for 2 dogs with unknown signalment. 1 Jul 2019*: The dogs began receiving FRONTLINE PLUS DOG 23-44 LBS (S61727AL) monthly with 3 vials purchased on an unknown date from Tractor Supply. The product was applied directly on the skin between the shoulder blades. Fleas were seen for several months prior to product application. Prior to starting the product, the pet owner was using Advantage to no avail. 1 Aug 2019*: The monthly dose was applied. The product was applied directly on the skin between the shoulder blades. Fleas were seen prior to product application. 28 Aug 2019: The dogs were bathed with Sergeants flea and tick shampoo. 30 Aug 2019: The owner is still noticing severe fleas. The dogs have access to an open area with trees and a hedgerow. The dogs have not presented to the veterinary clinic. The pet owner occasionally sprays the dogs with an unknown all natural flea spray. The dogs' current condition is ongoing. There a total of 2 canines in the household. No further medical information expected. UPDATE 12 Sep 2019: Case changed to an inquiry due to preexisting fleas and less than 3 months administered. UPDATE 2 Oct 2019: The owner applied the 3rd vial 1 Sept 2019.

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ED_005739D_00014391-00239

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											The issue is still ongoing.
18-Nov-2019	UAE; 19US052479; VA; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Aug-2019*	18-Nov-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 3 Sep 2019, a pet owner reported the following event for Geo, a 15 pound, 6 year old, neutered male, Shih-Tzu. 18 Aug 2019: The pet owner saw that the dog was scratching constantly. The owner bathed the dog in Dawn dish soap and noticed that the dog had 5 dead fleas on him. The dog is indoor/outdoor but spends the majority of the time indoor. The dog has access to a front yard where there is grass and 1 tree. 27 Aug 2019: The pet owner purchased and applied for the first time 1 dose of FRONTLINE PLUS DOG 5-22 LBS (unknown lot number, package unavailable), topically between the shoulder blades. The owner applies flea and tick to the dog seasonally and this was the first dose of the season. 3 Sep 2019: The owner noticed that the dog had about 3-5 fleas on him. The owner has a housemate with the same issue see case 19US052472. The issue is ongoing. No further medical information expected. UPDATE 16 Sep 2019: Case changed to an inquiry due to preexisting fleas and only one dose administered. UPDATE 18 Nov 2019: Pet owner called back in with update on use of product. 27 Sep 2019* and 27 Oct 2019*: The pet owner applied the FRONTLINE PLUS. 18 Nov 2019: The pet owner is still noticing an unknown amount of fleas. No further medical information expected.
02-Oct-2019	UAE; 19US052527; IN; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Jul-2019	02-Oct-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 03 Sep 2019, animal owner reported the following event for 2, 4 month old cats. All signalment is unknown. 12 Jul 2019: The pet owner noticed live fleas on the cats. The number of fleas are unknown. 16 Jul 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (S41307AW) topically for the first time. 19 Aug 2019: The pet owner saw live fleas on both cats and applied a second dose. The pet owner is still seeing fleas on both cats. The pet owner could not provide the number of fleas seen on both cats. Both cats are indoor only. No further information expected. UPDATE 16 Sep 2019: Case updated to Inquiry due to treatment program not respected. UPDATE 2 Oct 2019: As per the owner, she applied the product to both pets 16 Sep 2019*. The pet owner is continuing to see fleas on the pets. The owner is not seeing fleas in the home. No further medical information expected.
22-Oct-2019	UAE; 19US053962; ME; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 6 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Capstar; **Route:** Topical / Cutaneous **Was the**	17-Jul-2019*	10-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 10 Sept 2019, the pet owner reported the following event for Sophie, a 5 year old 6 pound female spayed Domestic Shorthair. 17 Jul 2019* and 16 Aug 2019: The pet owner applied a dose of FRONTLINE PLUS CATS (S41108AW) down to the skin between the shoulder blades for the first time because fleas were seen in the home starting in Jun 2019*. The cat was also given Capstar. 10 Sept 2019: The pet owner had not seen fleas for a week or so and then found five fleas on the cat. The cat stays inside, though had gotten out in Jun 2019*. There is a dog in the home who does not have fleas and is on Bravecto. The home has been treated

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ED_005739D_00014391-00240

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					several times. The cat is not bathed. The cat was given Capstar again. No further medical information expected. UPDATE 20 Sept 2019: Case changed to inquiry based off treatment program not respected. Product has not been used for a minimum of 90 days. UPDATE 22 Oct 2019: Per the owner, most recent dose of FRONTLINE was applied 13 Oct 2019. Owner has been treating monthly. Owner is still finding fleas on the cats. No further medical information expected.
25-Oct-2019	UAE; 19US054357; GA; U.S.A	**Species:** Canine **Breed:** Boston Terrier **Sex:** F **Sex qualifier:** Lactating **Age:** - **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	31-Aug-2019	25-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Sep 2019, the pet owner reported the following issue for a 15 pound*, non-pregnant lactating female Boston Terrier. 31 Aug 2019: After seeing an unknown number of fleas on the dog, the owner applied 1 dose of FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown, package unavailable) topically between the shoulder blades for the first time. 11 Sep 2019: The owner continues to see fleas on the dog as well as on the dog's 4 puppies who were not treated with any preventative. It is unknown if any fleas have been seen in the home and there are no other animals in the home. The dogs are indoor only. No further medical information expected. UPDATE 24 Sep 2019: Case changed to an inquiry due to preexisting fleas and only one dose administered. UPDATE 25 Oct 2019: Another vial was applied Sept 2019* and Oct 2019*. The flea issue is still ongoing. No further information expected. UPDATE 11 Nov 2019: Per the pet owner, the lot number is S61006AL. No further medical information expected.
28-Oct-2019	UAE; 19US054566; NJ; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** - **Age:** 1.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Pet Action Plus; Unknown dewormer; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Aug-2019	29-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: 12 Sep 2019: An owner reported the following event in Kitty, a 1 year old, 8 pound, intact, female, Domestic Longhair. 29 Aug 2019: The owner administered one FRONTLINE PLUS CATS (S40606AW) topically at the base of the skull for the first time. 10 fleas were seen at the time of application. The cat had hair loss and scabs around the next prior to application. 12 Sep 2019: The cat has 12 fleas on her. The cat is indoor only in an unknown environment. There is one dog in the home (19US54571). No further medical information expected. UPDATE 25 Sept 2019: Case changed to inquiry based off treatment program not respected. Product has not been used for a minimum of 90 days. UPDATE 28 Oct 2019: Per a conversation with the owner, June 2019*: The owner noticed an unknown amount of fleas on the pet and applied Pet Action Plus to the pet. The pet had been scratching uncontrollably and started to have hair loss. 29 Jul 2019: The pet is continuing to scratch and have hair loss. An unknown amount of fleas were seen on the pet. The owner started FRONTLINE PLUS CATS (lot unknown, package unavailable) topically between the shoulder blades for the first time. 29 Aug 2019: The pet is continuing to scratch and have hair loss. The owner continued to see an unknown amount of fleas on the pet and applied FRONTLINE PLUS. 29 Sep 2019: The pet is continuing to scratch and have hair loss. The owner continued to see an unknown amount of fleas on the pet and applied FRONTLINE PLUS.

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ED_005739D_00014391-00241

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											Unknown Date: Per the owners sister, a veterinarian technician, the pet was diagnosed and treated for tapeworm with an unknown dewormer. The pet was not seen by a veterinarian. There is an unknown amount of fleas seen in the home. The owner bathed the pet with an unknown pet shampoo on unknown dates. The pet continues to loose hair and scratch, the pet has not been brought to a veterinarian for this condition. The owner continues to see fleas on the dog in the home,
28-Oct-2019	UAE; 19US054571; NJ; U.S.A	**Species:** Canine **Breed:** Pointer (German Short-Haired) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 68 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Pet Action Plus; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Jul-2019	28-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: 12 Sep 2019: An owner reported the following event in Delilah, a 3-year-old, 68 pound, spayed, female, German Short hair pointer mix. 29 Aug 2019: The owner administered one FRONTLINE PLUS DOGS 45-88 LBS (S63106AX) topically in-between the shoulders for the first time. 2 fleas were seen at the time of application. 12 Sep 2019: The dog has 2 fleas on her. The dog is indoor-outdoor in an unknown environment. There is one cat in the home (19US054566). No further medical information expected. UPDATE 24 Sep 2019: Case changed to an inquiry due to preexisting fleas and only one dose administered. UPDATE 28 Oct 2019: Per a conversation with the owner, June 2019*: The owner noticed an unknown amount of fleas on the pet and applied Pet Action Plus to the pet. 29 Jul 2019:An unknown amount of fleas were seen on the pet. The owner started FRONTLINE PLUS DOGS 45-88 LBS (S63106AX) topically between the shoulder blades for the first time. 29 Aug 2019: The owner continued to see an unknown amount of fleas on the pet and applied FRONTLINE PLUS. 29 Sep 2019: The owner continued to see an unknown amount of fleas on the pet and applied FRONTLINE PLUS. 27 Oct 2019: The owner continues to see fleas on the pet and applied FRONTLINE PLUS. 28 Oct 2019: The pet was outside and came in the house with 3 live fleas on the pet. The owner removed the fleas. There is an unknown amount of fleas seen in the home. The owner bathed the pet with an unknown pet shampoo on unknown dates. The owner continues to see fleas on the cat in the home, see case 19US054566. No further medical information expected.
01-Nov-2019	UAE; 19US054810; MA; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 15 - 17 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Aug-2019	13-Sep-2019	12 Day(s)	D-D	Suspected Lack of Efficacy: On 13 Sep 2019, the pet owner reported the following event for a 15 to 17 pound*, male neutered, small crossbred. 1 Aug 2019: The dog was a adopted and had fleas. The owner applied 1 vial of FRONTLINE PLUS DOG 5-22 LBS(S62106AL) to the dog in one area between the shoulder blades for the very first time. 30 Aug 2019: There were 10+ fleas on the dog. The owner bathed the dog in a No Shed pet shampoo. 1 Sep 2019: There were 10+ fleas on the dog, 1 vial of FRONTLINE was applied. 13 Sep 2019: There are 10+ fleas on the dog from nose to tail per the pet owner. There are fleas in the home biting the humans. There are 2 indoor only cats who are treated with FRONTLINE and having an issue with fleas, see case 19US54815. No further information. UPDATE 26 Sep 2019: Case updated to inquiry due to treatment program not respected. UPDATE 1 Nov 2019:

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ED_005739D_00014391-00242

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											1 Oct 2019: Applied another dose. 1 Nov 2019: Owner is continuing to see fleas.
22-Nov-2019	UAE; 19US054892; MD; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 14 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Sep-2019	12-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 13 Sep 2019, the owner reported the following event for a 14 pound feline (all other signalments unknown). 11 Sep 2019: First dose of FRONTLINE PLUS CATS (S41004AW) topically between the shoulder blades by the owner. The cat had fleas prior to the first dose. 12 Sep 2019*: The owner continued to see fleas on the cat. The owner is still seeing a large amount of fleas on the cat. The owner is not seeing fleas in the home. The cat is strictly indoors. No further medical information expected. UPDATE 26 Sep 2019: Case updated to inquiry due to treatment program not respected. UPDATE 22 NOV 2019: Suspected Lack of Efficacy Claim and Suspected Adverse Event: 11 Oct 2019: Owner applied the monthly dose. 10 Nov 2019: Owner applied the monthly dose. The owner noticed the pet now has bumps on the back of her neck. Owner has seen fleas on the pet since 12 Sep 2019*. No further medical information expected.
26-Nov-2019	UAE; 19US055602; WV; U.S.A	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** X **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 15 - 20 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Sep-2019*	17-Sep-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Sep 2019, a pet owner reported the following event for 2, 8-10 year old, 15-20 pound, mixed sex, neutered Jack Russell Terrier mixes. 12 Sep 2019*: The dogs each received 1 application of FRONTLINE PLUS DOG 5-22 LBS (S61902AL) topically between the shoulder blades in one spot for the first time. The dogs had a few fleas prior to putting the FRONTLINE on and they were scratching. The owner also sprayed the house with a flea spray before applying the FRONTLINE. 17 Sep 2019*: The dogs were scratching and the owner noticed a few live fleas on them. The pet owner is not noticing any flea activity inside of the home. The dogs go outside and chase squirrels. There are no other pets in the home. It is unknown if the dogs receive baths. No further information expected. UPDATE 29 Sep 2019: Case updated to inquiry due to treatment program not respected. UPDATE 26 Nov 2019: Per letter received from pet owner: Unknown Date: One of the dogs also had ticks on them after FRONTLINE application. It is unknown if they were attached or engorged. It is unknown if they were removed. No further information expected.
16-Dec-2019	UAE; 19US056661; MD; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 75 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No	01-Sep-2019*	01-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, the pet owner reported the following event for a 75 pound* German Shepherd Dog with otherwise unknown signalment. 1 Sep 2019*: The dog began receiving FRONTLINE PLUS DOG 45-88 LBS (S61810AX) monthly with 3 vials purchased from an unknown source. Product application details are unknown. Fleas were seen for 1 month prior to product application. 15 Sep 2019*: The most recent application. Product application details are unknown. Fleas were seen for 1 month prior to product application. 23 Sep 2019: The owner is still noticing an unknown amount of fleas. The dog's excursion details are unknown. It is unknown if the dog presented to the veterinary clinic. It is

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ED_005739D_00014391-00243

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						(Treatment / vaccination program not respected)					unknown if treatments have been provided at home. The dog's current condition is ongoing. There a total of 1 canines and 3 felines in the household. The cat's excursion details are unknown, and they are on an unknown Hartz topical product. No further medical information expected. UPDATE 4 OCT 2019: Case changed to Inquiry due to treatment program not respected. UPDATE 15 Oct 2019: The owner applied FRONTLINE PLUS to the pet. 18 Oct 2019: The owner continues to see an unknown amount of fleas on the pet. No further medical information expected. UPDATE 16 Dec 2019: 15 Nov 2019*: The owner applied another dose and is still seeing fleas. 16 Dec 2019: The owner is still seeing fleas. It is unknown if the owner applied another dose on 15 Dec. No further medical information expected.
20-Dec-2019	UAE; 19US057188; NJ; U.S.A	**Species:** Canine **Breed:** Rottweiler **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 125 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Natures Miracle used as a shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Aug-2019*	23-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, a pet owner reported the following event in Luke, a 3 year old*, 125* pound, neutered male, Rottweiler canine. 1 Aug 2019*: The owner noticed the dog had fleas present and was very itchy. 21 Aug 2019*: The owner gave the dog a bath with Nature's Miracle. 22 Aug 2019*: The dog received its first application of FRONTLINE PLUS DOG 89-132 LBS (S62006RX) in between the shoulder blades. Prior to this the dog was not on flea prevention this year. 23 Aug 2019*: The owner continued seeing fleas on the dog, but not in the environment. 20 Sep 2019: The owner gave the dog a bath with Nature's Miracle. 21 Sep 2019: The dog received its second application of FRONTLINE PLUS DOG 89-132 LBS (S62006RX) in between the shoulder blades. 22 Sep 2019: The owner continued to see fleas on the dog; the owner has not stopped seeing fleas after the first application of FRONTLINE PLUS. The fleas are near his tail and he is still itching. The dog has access to the back yard, porch and is walked to a park regularly. The owner reports there is not a lot of wildlife in the area and has not seen a lot of stray cats. The owner is not being bitten by fleas and is still not seeing them in the environment. There are no other animals in the home. No further medical information expected. UPDATE 08 Oct 2019: Case updated to inquiry due to treatment program not respected. UPDATE 20 Dec 2019: pet owner called in to report the following. 22 Oct 2019*: pet owner gave the third dose of FRONTLINE PLUS DOG 89-132 LBS (S62006RX) to the pet. UNKNOWN DATE: Pet owner brushed the pet and notice an unknown amount of fleas being brushed off. Pet owner states that the pet is chewing at the tail still and causing minor bleeding due to the fleas. 19 Dec 2019*: pet owner brushed 12+ fleas off the pet. The pet owner continues to see fleas after the third dose but did state that the amount of fleas seen have lessened but the pet is still itchy from the

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Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
15-Nov-2019	UAE; 19US057643; TX; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 13 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Sep-2019	14-Nov-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Sep 2019, the pet owner reported the following event for two 13 pound* felines of further unknown signalment. 31 Jul 2019*: The reporter began noticing an unknown volume of fleas on both indoor-only cats. Neither feline had been receiving any form of flea control. The pet owner elected to just comb the fleas off of said felines and continued to do so for an unknown duration. Unknown date: An unknown duration after initially seeing fleas, the reporter saw both cats scratching a lot which is what prompted her to start using flea control. 5 Sep 2019: She applied one vial per cat of FRONTLINE PLUS CAT (lot unknown; package unavailable) topically between the shoulder blades for the first time. At the time of application, both felines were pruritic and both had a medium volume of fleas on their bodies. The fleas seemed to be most prevalent around their necks and under their chins. Unknown date: An unknown duration following product application, the reporter continued to see a medium volume of fleas on both felines who also remained pruritic. Presently, the reporter continues to find a medium volume of fleas per feline and both cats are still itchy. The reporter has not found any fleas in the home nor have there been any visiting animals. There are no other resident animals present. No further medical information expected. UPDATE 10 Oct 2019: Case changed to an inquiry due to preexisting fleas and less than 3 months administered. UPDATE: 14 Nov 2019: Owner called back reporting continuing flea burden after applying 3 monthly doses of FRONTLINE PLUS CATS to each cat. 5 Oct 2019: Applied one vial per cat of FRONTLINE PLUS CAT (S41305AW) topically between the shoulder blades. * Oct 2019: Owner had exterminator come out and treat home. 5 Nov 2019: Applied a vial per cat of FRONTLINE PLUS CAT (S41305AW) topically between the shoulder blades. The pet owner hascontinued to see fleas since the first applicatoon in Sep. The cats
01-Oct-2019	UAE; 19US058265; VA; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 75 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Aug-2019	01-Oct-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, a pet owner reported the following event for Kizer, a 10 year old, 75 pound, male neutered, German Shephed. 22 Aug 2019: The owner applied the first dose of FRONTLINE PLUS DOG 45-88 LBS (S61314) and no fleas were present. 22 Sep 2019: The owner applied the second dose. 1 Oct 2019: The owner noted the dog is infested with fleas. The dog goes outside for bathroom breaks and playtime. There are 2 cats in the house having the same issue, see case 19US058274. No further medical information expected. UPDATE 4 Nov 2019: The last application was applied 22 Oct 2019. No fruther medical information expected.
01-Oct-2019	UAE; 19US058270; MI; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	26-Aug-2019	30-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for Pippi, an 18 month old*, female, 20 pound, Mixed breed. 26 Aug 2019: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (S61006AL). The product was applied directly on the skin between the shoulder blades. Fleas were not seen prior to

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ED_005739D_00014391-00245

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 18.00 Month(s) **Weight:** 20 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					product application, but dog was itching some. 30 Aug 2019*: The pet owner noticed a few fleas. The dog is still itching some as well. The dog has access to a fenced in yard, with trees and brush on the property. The dog also like to play in the flower beds. The dog does not go on walk or to the dog park or groomer. 7 Sep 2019*: The pet owner bathed the dog in a pet shampoo. 18 Sep 2019: The most recent date of application. The pet owner is still noticing fleas. The dog's current condition is ongoing. This is the only pet in the household. No more information expected.
01-Oct-2019	UAE; 19US058274; VA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Aug-2019	01-Oct-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, a pet owner reported the following event for 2 cats of unknown signalment. 22 Aug 2019: The owner applied the first dose of FRONTLINE PLUS CATS (S41006) and no fleas were present. 22 Sep 2019: The owner applied the second dose. 1 Oct 2019: The owner noted the cats were infested with fleas. The cats are indoor only. There is 1 dog in the house having the same issue, see case 19US058265. No further medical information expected.
01-Oct-2019	UAE; 19US058281; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 150 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	01-Aug-2019*	28-Sep-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the owner reported the following event for a 5 years old, 150 pounds, canine (all other signalments unknown). Unknown date: The pet owner uses the FRONTLINE PLUS in the warmer months of the year but is not consistent. 25 Sept 2019: The most recent vial of FRONTLINE PLUS DOG 89-132 AND FRONTLINE PLUS DOG 5-22 LBS (lots unknown, package unavailable) was applied between the shoulder blades, by the pet owner. 28 Sept 2019: The dog had small amount of fleas for the first time. The dog does not get bathed. The owner is noticing flea activity in the household. The dog has access to an unknown area for bathroom breaks. There is 1 cat in the household that uses FRONTLINE PLUS but is not having no issues with fleas. No further medical information is expected.
01-Oct-2019	UAE; 19US058284; MI; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Week(s) **Weight:** 3 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	01-Oct-2019	01-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 1 Oct 2019, the owner reported the following event for Ghost, a 9 week old*, 3 pound, female intacted Domestic Shorthair. 1 Oct 2019: The pet received FRONTLINE PLUS CATS (S40815AW) topically between the shoulder blades. This is the first application. About 5 minutes later, the pet vomited once. No treatment was given. The pet recovered after an unknown amount of time. The pet has no pertinent medical history. The pet has no history of drug reactions. No further medical information expected.

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ED_005739D_00014391-00246

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					
01-Oct-2019	UAE; 19US058302; PA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 13 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Sep-2018	06-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for Ollie, a 7 year old, neutered male, 13 pound, Domestic Longhair. 7 Jun 2019: The cat began receiving FRONTLINE PLUS CATS (R41105AW) monthly. The product was applied directly on the skin between the shoulder blades. Fleas were not seen prior to product application. 5 Sep 2019: The most recent date of application. 6 Sep 2019*: The owner is noticing fleas. The cat has access to a open yard, with trees and brush in the yard. The cat does have access to areas under decks/crawl spaces. No treatments have been provided at home. The cat's current condition is ongoing. This is the only pet in the household. The cat has no history of drug or vaccine reactions. No further medical information expected.
01-Oct-2019	UAE; 19US058315; LA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	21-Sep-2019*	22-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019 the pet owner reported the following event via mail for two canines of unknown signalment. Unknown date: The two canines started on FRONTLINE PLUS DOG 5-22 LBS (S61017AL), unknown dose, route, or application site, monthly. 21 Sep 2019*: The most recent dose was applied to the two canines. There were an unknown number of fleas on the canines at the time of application for an unknown amount of time. 22 Sep 2019*: The pet owner reports she was still seeing fleas on both pets. It is unknown where the canines spend the majority of the time or what outside areas they have access to. It is also unknown if there are any other pets in the household. No further medical information is expected. UPDATE: 8 Oct 2019: 2018*: The pets began receiving FRONTLINE PLUS 5-22 LBS (lot unknown) (package unavailable), applied 1 vial per animal topically between the shoulder blades monthly. 21 Jul 2019: A monthly dose was applied. 21 Aug 2019: A monthly dose was applied.
01-Oct-2019	UAE; 19US058322; OH; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** - **Age:** 16.00 Year(s) **Weight:** 17 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Hartz brand shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	07-Sep-2019*	10-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for Cujo, a 16 year old, 17 pound*, intact male, Maltese. 7 Sep 2019*: The canine began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (S61902AL) (FL+) applied topically between the shoulder blades. This was Cujo's first application of 2019 and fleas were not seen on him at the time of product application. One vial of FL+ has since been applied in the same fashion on the following dates: 14 Sep 2019 and 28 Sep 2019. It's unknown if Cujo has ever previously received FL+. Unknown dates: Two or three days following initial FL+ application, the pet owner began seeing an unknown volume of fleas on the dog. Then around 13 Sep 2019* or 14 Sep 2019*, he saw a single flea on Cujo, and by 26 Sep 2019* or 27 Sep 2019* he was seeing a medium volume of fleas on Cujo. Presently, the pet owner continues to see a medium volume of fleas on the canine, but is not finding any fleas in the home. Fleas were on the dog at the time the second and third applications of

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ED_005739D_00014391-00247

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											FL+ were applied. There are no other resident or visiting animals in the home and the dog lives in the city where he has access to a small yard. The external environment is otherwise unknown. No further medical information expected.
01-Oct-2019	UAE; 19US058328; IN; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jul-2019*	29-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 1 Oct 2019, the pet owner reported the following event for two 4 year old cats with otherwise unknown signalment. Unknown date: The cats presented to the veterinary clinic for fleas. It is unknown if diagnostics were performed. It is unknown if treatments were provided in clinic, but the veterinarian recommended Frontline use. 1 Jul 2019*: The cats began receiving FRONTLINE PLUS CATS (lot unknown, package unavailable) monthly with 3 vials purchased on an unknown date from an unknown source and 6 vials purchased on 17 Sep 2019 from Amazon. The product was applied directly on the skin on the back of the neck. Fleas were seen for 4 weeks prior to product application. 1 Aug 2019*, 1 Sep 2019*, and 29 Sep 2019: The monthly dose was applied. After each dose, the cats are lethargic for a few days, but return to normal without any treatment. 1 Oct 2019: The owner is still noticing an unknown amount of fleas. The cats are indoor/outdoor. The cats' current condition is ongoing. There a total of 2 felines in the household. The pet owner routinely bathes the cats up to 3 times per week with Dawn dish detergent, last date unknown. No further medical information expected.
01-Oct-2019	UAE; 19US058354; MO; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 85 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Sep-2019	01-Oct-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, a pet owner reported the following event for Kora, a 5 year old, 85 pound, spayed female mixed breed. 2015: The owner started using FRONTLINE PLUS DOG 45-88 (S62503AXR) monthly topically between the shoulder blades. 25 Sep 2019: The most recent dose was applied and no fleas were seen at the time of application. 1 Oct 2019: Fleas were seen. No other pets are in the house. All other details are unknown. No further medical information expected.
01-Oct-2019	UAE; 19US058358; IN; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Sep-2019*	01-Oct-2019*	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for a German Shepherd Dog with otherwise unknown signalment. 2018*: The dog began receiving FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) monthly with unknown purchase history. Product application details are unknown. It is unknown if fleas or ticks were seen prior to product application. The pet owner applies the product monthly, but the most recent date of application is unknown. The dog's previous Lyme test history is unknown. 1 Oct 2019*: The dog presented to the veterinary clinic for a routine wellness exam. The dog was diagnosed Lyme antigen positive via an unknown test. It is unknown if a Quant C6 has been performed. It is unknown if treatments have been provided. The dog's current condition is ongoing. It is unknown if there are any other animals in the household. No further medical information expected.

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ED_005739D_00014391-00248

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
01-Oct-2019	UAE; 19US058365; ME; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 90 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	24-Sep-2019	29-Sep-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for Fenway, a 7 year old*, 90 pound, neutered male, Golden Retriever. Unknown dates: The canine has received one vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown; package unavailable) applied topically between the shoulder blades seasonally during unknown fall and possible winter months spanning an unknown period of time. Unknown date: Fenway became pruritic. 24 Sep 2019: Due to the ongoing pruritus, the reporter applied one vial of FRONTLINE PLUS DOG 89-132 LBS (R60908) in the same manner as previously described. It's unknown if fleas were present at the time of application because the reporter did not check the dog. 29 Sep 2019: The reporter noticed an unknown amount of flea dirt on Fenway so he bathed with an unknown flea shampoo. During the bath, he noticed a small amount of fleas on the dog as well. 1 Oct 2019: The reporter continues to find an unknown volume of flea dirt on Fenway. Fleas have not been observed in the home where there are no other resident or visiting animals. Fenway stays outside all day with the reporter while he's at work. The canine has access to a 10 acre field with lots of hay and particularly during the fall and possibly winter months, the dog has exposure to chickens and turkeys. No further information regarding the dog's external environment can be confirmed. No further medical information expected.
01-Oct-2019	UAE; 19US058391; OR; U.S.A	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Sep-2019	01-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for 2 dogs, miniature poodles, with remaining signalment unknown. Unknown date: The dogs have received FRONTLINE PLUS DOG 5-22# LBS monthly seasonally, including an unknown date in Aug 2019*. 30 Sep 2019: The dog received FRONTLINE PLUS DOG 5-22# LBS (S60810AX). The product was applied directly on the skin between the shoulder blades. Fleas were seen prior to this product application, and both dogs were scratching as well. 1 Oct 2019: The owner is still noticing fleas. The dog has access to a fenced in yard, with trees and brush on the property. The dogs do go on daily leash walks as well. The dog's current conditions are ongoing. These are the only pets in the household. No further medical information expected.
01-Oct-2019	UAE; 19US058413; MI; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 52 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment /	12-Aug-2019*	17-Sep-2019*	5 Week(s) 1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, a pet owner reported the following event for Bear, a 6* year old (born 13 Feb 2013*), 52 pound, neutered male Pit Bull. 2013*: The dog began receiving monthly applications of FRONTLINE PLUS DOG 45-88 LBS (Lot Unknown, Package Unavailable) topically between the shoulder blades in one spot during the spring and summer months. 11 Jul 2019: The dog received 1 application of FRONTLINE PLUS DOG 45-88 LBS (M64501AR) for the first time this year. The owner was not seeing fleas prior to application. 12 Aug 2019*: The dog received another application of FRONTLINE. 17 Sep 2019*: The pet owner noticed the dog scratching and saw approximately 15 live fleas on the dog.

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ED_005739D_00014391-00249

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						vaccination program not respected)					21 Sep 2019: Another application of FRONTLINE was applied. 26 Sep 2019: The dog was bathed with a flea shampoo. The owner also applied a flea powder to her carpets. There are no other pets in the home but the dog does come in contact with other dogs in the neighborhood. The yard is fenced in and there are no decks or crawl spaces. There are 2 large trees on the property. The owner is not getting bit by fleas but has noticed some fleas on the couch and floor. No further information expected.
01-Oct-2019	UAE; 19US058483; OH; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Revolution; Pet Armour Plus; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	17-Sep-2019	18-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for 4 cats of unknown signalment. Unknown date: The cats began receiving occasional seasonal monthly doses of FRONTLINE PLUS CATS (S41404AW). The owner also uses Revolution and Pet Armour Plus. 17 Sep 2019: The most recent dose of application. The product was applied directly on the skin between the shoulder blades. Fleas were seen prior to product application. 18 Sep 2019: The owner is still noticing fleas. One cat does have access to an outdoor area, three of the cats are indoor only. It is unknown the area the cat frequents. Sep 2019*: the pet owner did spray the home with Raid Flea spray. The cat's current conditions are ongoing. There a total of the four felines in the household. No further medical information expected.
01-Oct-2019	UAE; 19US058488; -; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 16 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Sep-2019	12-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for two 16 pound*, 4 year old* dogs with otherwise unknown signalment. 2015*: The dogs began receiving FRONTLINE PLUS DOG 5-22 LBS (T60214AL) monthly with 6 vials purchased on an unknown date from Chewy.com. The product was applied directly on the skin between the shoulder blades. Fleas were not seen prior to product application. 17 Jul 2019: The monthly dose was applied. 12 Aug 2019: The pet owner noticed fleas on the dogs after visiting the groomer. 17 Aug 2019: The monthly dose was applied. 16 Sep 2019: The monthly dose was applied. 1 Oct 2019: The owner is still noticing moderate fleas. The dogs have access to a fenced yard and go on leash walks to the park. The pet owner lives in the woods and frequently see wildlife. The dogs have not presented to the veterinary clinic. No treatments have been provided at home. The dogs ' current condition is ongoing. There a total of 2 canines and 1 indoor/outdoor feline in the household. The cat is on FRONTLINE PLUS CATS, but is not experiencing fleas. Caller declined to answer further questions. No further medical information expected.
01-Oct-2019	UAE; 19US058505; MD; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Chocolate) **Sex:** M **Sex qualifier:** - **Age:** - **Weight:** 80 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** dog shampoo;	30-Jul-2019*	30-Jul-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the owner reported the following event for an 80 pound, intact male Chocolate Labrador Retriever. *30 Jul 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S60502AX) was applied to the skin between the shoulder blades. *Unknown date: The owner started to notice fleas. *30 Aug 2019: The dog still had fleas and another application was given.

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ED_005739D_00014391-00250

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** Yes					30 Sept 2019: The dog continued to pick up fleas and another application was given. The dog has been having fleas issues for the past 2 months and is treated with FL year round. The dog is exposed to grass and woods daily. The dog is bathed once a week in dog shampoo, there aren't any fleas in the home. There is one cat who uses a flea collar. No further information available.
01-Oct-2019	UAE; 19US058521; PA; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 92 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Jun-2019*	14-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for a 92 pound dog with otherwise unknown signalment. 11 Jun 2019*: The dog began receiving FRONTLINE PLUS DOG 89-132 LBS (S62311AX) monthly with 3 vials purchased on an unknown date from Walmart. The product was applied directly on the skin between the shoulder blades. Fleas were seen prior to product application. 14 Jul 2019*, 11 Aug 2019*, and 15 Sep 2019*: The monthly doses were applied. The pet owner continued to see fleas throughout. 1 Oct 2019: The owner is still noticing severe fleas. The dog has access to an open area and lives in the country on 80 acres of land with surrounding woods. The dog has not presented to the veterinary clinic. The pet owner gave Capstar on an unknown date. The dog's current condition is ongoing. There a total of 1 canines and 2 indoor felines in the household. The cats in the home are experiencing similar symptoms, see case 19US058621. No further medical information expected.
01-Oct-2019	UAE; 19US058523; -; U.S.A	**Species:** Feline **Breed:** - **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	08-Sep-2019	12-Sep-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the owner reported the following event for 4 felines with unknown signalment. Sep 2019*: The owner noticed a small amount of fleas on the pets. 8 Sep 2019: One dose each of FRONTLINE PLUS CATS (product unsubstantiated)(lot unknown) was applied topically, in between the shoulder blades. 12 Sep 2019*: The owner saw a small amount of fleas on the pets. 1 Oct 2019: The owner reports still seeing a small amount of fleas. The pets are considered indoor cats. There were a small amount of fleas seen prior to product use. There are 3 other cats in the home that are also on FRONTLINE FOR DOG (product unsubstantiated)(lot unknown) that also has fleas (Please see case 19US058506). The owner has been treating monthly with FRONTLINE since an unknown amount of time. No further information at this time.
01-Oct-2019	UAE; 19US058524; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 17.8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Sep-2019	29-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the owner reported the following event for a 17.8 pound dog (other signalment unknown). 28 September 2019: The dog was scratching (no fleas seen) so the owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable) topically to the skin between the shoulder blades for the first time. *Unknown date: The owner found 2 fleas. The dog's environment is unknown and it unknown how often the dog is bathed. There are no other dogs in the home, no further information available.

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ED_005739D_00014391-00251

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01-Oct-2019	UAE; 19US058543; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 19 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Jul-2019	17-Jul-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the owner reported the following event for two 19 pound dogs (further signalment unknown). 17 July 2019: The dogs had fleas and were treated with one vial of FRONTLINE PLUS DOG 5-22 LBS (S61718AL). 17 Aug 2019: The dogs still had fleas and were treated with one vial of FRONTLINE PLUS DOG 5-22 LBS (S61718AL). 17 Sept 2019: The dogs still had fleas and were treated with one vial of FRONTLINE PLUS DOG 5-22 LBS (S61718AL). Unknown date: The dogs are bathed with oatmeal shampoo and flea shampoo. The dogs are exposed to a treated yard daily and there aren't any fleas in the home. The dogs are treated monthly year round and has only had an issue for the past 3 months. The owner is finding a large number of fleas one dog and a small number of fleas on the other. There aren't any other pets in the home. No further information available.
01-Oct-2019	UAE; 19US058546; -; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 60 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jan-2016*	02-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019 the pet owner reported the following event for Selah a 3 year old*, 60 pound*, spayed female, Crossbred canine. Unknown Date: The owner sees fleas on the pet and in home. 1 Jan 2016* - 1 Jun 2019*: The pet owner applied an unknown amount of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) by an unknown route to an unknown location. 2 Jun 2019*: The pet owner continues to see fleas on pet and in home. 1 Jul 2019*: The pet administered 1 chew of NEXGARD, see case 19US058537 The pet has access to a grass yard, where urban wildlife is present. There are 2 cats in the home on Revolution for flea preventative. The pet is bathed on unknown dates with an unknown pet approved shampoo. No further medical information expected.
01-Oct-2019	UAE; 19US058554; MO; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 65 - 82 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Mar-2019*	10-Sep-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for Q-tip a 9 year old*, 82 pound*, spayed female, Black lab cross and Dandylion, a 3 year old*, 65 pound*, spayed female Golden Retriever. 1 Mar 2019* - 1 Sep 2019*: The pet owner applies on vial of FRONTLINE PLUS DOG 45-88 LBS (S62408AX) topically between the shoulder blades to the pets. 10 Sep 2019: The pet owner noticed an unknown amount of fleas on the pets. 20 Sep 2019: The pet owner bathed Dandylion with an unknown pet approved shampoo 27 Sep 2019:The pet owner continues to see fleas on the pet. The pet owner bathed both pets in Dawn Dish soap. The pets have access outside to a grass lawn with trees shrubs and bushes. The owner confirms there is wildlife present in the yard. The pet owner brings the pets to a local dog park. There is also stray cats and dogs present on the owners property. The pet owner is seeing an unknown amount of fleas in the home. There is one cat in the home, see case 19US05881. No further medical information expected.
01-Oct-2019	UAE; 19US058563;	**Species:** Canine **Breed:** Yorkshire	1	1	0	**Product used:** FIPRONIL	01-Jan-2018*	01-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for Luna, a 2 year old*, 18 pound*,

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ED_005739D_00014391-00252

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	TX; U.S.A	Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 18 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					spayed female, Yorkshire Terrier Schnauzer crossbred canine. 1 Jan 2018*-30 Sep 2019*: The pet owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS (T60613AL) topically between the shoulder blades. 1 Oct 2019: The pet owner noticed 2 fleas on the dog. The dog has access outside for leash walks and urban wildlife is seen on those walks. The pet also frequents dog parks and goes to the groomer regularly. The pet is bathed with unknown pet approved shampoo by the groomer on unknown dates. There are no fleas seen in the home. There are no other pets in the home. No further medical information expected.
01-Oct-2019	UAE; 19US058565; MA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 10 - 24 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** PO-Oral **Was the product used ok?:** Yes	11-Sep-2019	20-Sep-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for 2 felines unknown signalment weighing between 10 and 24 lbs. UNKNOWN 2018*: The pets began receiving monthly FRONTLINE PLUS CATS (Lot unknown) (package unavailable). Owner applied 1 vial topically between the shoulder blades. The pets are treated year round. 11 Sep 2019: The owner applied the most recent dose. 20 Sep 2019: The owner noticed large amount of fleas on the pets. 25 Sep 2019: The owner applied an additional dose. The owner has been noticing fleas off of the pet inside the home. Initially she was seeing 50+ fleas. Recently that number has decreased to about 10 fleas. The cats are indoor only. There are no other pets in the home. The pet have not presented to the veterinarian. No further medical information expected.
01-Oct-2019	UAE; 19US058567; KY; U.S.A	**Species:** Canine **Breed:** Belgian Malinois **Sex:** M **Sex qualifier:** - **Age:** 8.50 Year(s) **Weight:** 66 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2014*	30-Sep-2019*	20 Day(s)	D-D	Suspected Lack of Efficacy: On 1 Oct 2019, a pet owner reported the following event for Hank, an 8.5 year old, 66 pound, intact male, Belgian Malinois canine. 10 Sep 2019*: The dog received its most recent application of FRONTLINE PLUS DOG 45-88LBS (S62202AX) in between the shoulder blades. The owner has been applying FRONTLINE PLUS on the dog monthly since 2014*. The owner uses FRONTLINE PLUS year round. 30 Sep 2019*: The dog presented to an animal hospital for itching and biting his back end. The veterinarian expressed his anal glands and claimed this was the reason he was biting as his back end. 1 Oct 2019: The owner discovered an engorged, live brown dog tick on the dog in an unknown area and more than 40 fleas were present on the dog. The owner applied another dose of FRONTLINE PLUS to the dog and physically removed the tick from the dog. The owner suspected the dog was biting as his back end because of the fleas. The dog has access to a fenced yard. Urban wildlife frequent the area and the yard is surrounded by foliage and wooded areas. There are no other animals in the home. The home nor the yard have been treated with any pesticides. No further medical information expected.
02-Oct-2019	UAE; 19US058572; NY; U.S.A	**Species:** Feline **Breed:** Ragdoll **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 14.000 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products	15-Sep-2019	16-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the pet owner reported the following event for Frankie, a 3 year old, neutered male, 14 pound*, Ragdoll. 2017*: The cat began receiving monthly doses of FRONTLINE PLUS CATS (S41411AW) seasonally. Aug 2019*: The pet owner reports seeing a moderate amount of fleas on the pet. 15 Sep 2019: The most recent date of application. The product

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ED_005739D_00014391-00253

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** Yes					was applied directly on the skin between the shoulder blades. 16 Sep 2019: The owner is still noticing a moderate amount of fleas. The cat does have access to a fenced in area outside. The owner did take the cat to the groomer, where the cat was bathed in an unknown flea shampoo. The cat's current condition is ongoing. This is the only pet in the household. No further medical information expected.
02-Oct-2019	UAE; 19US058592; IL; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 65 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	30-Jul-2019*	30-Sep-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the pet owner reported the following event for Max, a 4 year old*, 65 pound*, neutered male, mix breed canine. 30 Jul 2019*: The pet owner applied one vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) topically between the shoulder blades for the first time. 25 Sep 2019*: The pet owner applied FRONTLINE PLUS to the pet. 30 Sep 2019*: The pet owner noticed hundreds of fleas on pet and a very large number in the home. The pet owner bathed the pet in Hartz flea and tick shampoo. The pet has access outside to a grass yard and there is a large amount of wildlife present. The pet was in good health and has no history of vaccine reactions. There is a Guinea pig in the home that does not have fleas on it and is kept separate from the other pets. There is a cat in the home with a few fleas on him, see case 19US058601. no further medical information expected.
02-Oct-2019	UAE; 19US058593; OH; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 6 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Sep-2018*	30-Sep-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for a 6 pound Chihuahua with otherwise unknown signalment. 2018*: The dog began receiving FRONTLINE PLUS DOG (unsubstantiated) (lot unknown, package unavailable) monthly with unknown purchase history. Product application details are unknown. Fleas were not seen prior to product application. 30 Sep 2019: The pet owner noticed 1-2 fleas. The dog received a bath with an unknown flea shampoo. The dog was towel-dried. The monthly dose was applied a few hours later when the dog was dry. 2 Oct 2019: The owner is still noticing mild fleas. The dog goes for daily leash walks in the park. The dog has not presented to the veterinary clinic. No treatments have been provided at home. The dog's current condition is ongoing. There a total of 1 canines and no other animals in the household. No further medical information expected.
02-Oct-2019	UAE; 19US058601; IL; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 14 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Sep-2019*	30-Sep-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy: On 2 Oct 2019, the pet owner reported the following event for Spencer a 1 year old*, 14 pound, neutered male, Domestic Shorthair. 30 Jul 2019*: The pet owner applied one vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) topically between the shoulder blades for the first time. 25 Sep 2019*: The pet owner applied FRONTLINE PLUS CATS to the pet. 30 Sep 2019*: The pet owner noticed a few fleas on pet and a very large number in the home. The pet has access outside to a grass yard and there is a large amount of wildlife present. The pet was in good health and has no history of vaccine reactions. There is a Guinea pig in the home that does not have fleas on it and is kept separate from the other pets. There is a dog in the home with a large amount of fleas on him,

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ED_005739D_00014391-00254

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											see case 19US058592. no further medical information expected.
02-Oct-2019	UAE; 19US058609; WI; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Others)	01-Sep-2019*	01-Sep-2019*	0 Day(s)	D-C	Suspected Adverse Event: On 2 Oct 2019, the pet owner reported the following event for a feline of unknown signalment. Sep 2019*: The cat began receiving one vial of FRONTLINE PLUS DOG 45-88 LBS (R41105) monthly. The cat began experiencing neurological signs. Unknown date: The cat presented to the veterinary clinic. It is unknown if diagnostics were performed. It is unknown if treatment has been provided. The cat's current condition is unknown. The product applied was contained in a FRONTLINE PLUS CAT box - See Case # 19US058585. No further medical information expected.
02-Oct-2019	UAE; 19US058613; OH; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	02-Sep-2019*	02-Oct-2019*	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the pet owner called and reported the following for a canine of unknown signalment. Unknown date: Pet owner applied FRONTLINE PLUS DOG 5-22 LBS (unsubstantiated) (lot unknown, reporter refused). An unknown volume per animal via an unknown route at an unknown location. 2 Oct 2019*: Pet owner seeing fleas on the canine. It is unknown if the dog presented to a veterinary clinic. It is unknown if any treatments have been administered. Their current condition is unknown. It is unknown what environment the canine frequents. It is unknown if the owner bathes the canine. It is unknown if there are any other pets in the household. The dog has previously received FRONTLINE PLUS at unknown intervals for an unknown length of time. This is the extent of information known as caller refused to report. No further medical information expected.
01-Oct-2019	UAE; 19US058621; PA; U.S.A	**Species:** Feline **Breed:** Feline various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Jun-2019*	14-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, the pet owner reported the following event for 2 cats with unknown signalment. 11 Jun 2019*: The cats began receiving FRONTLINE PLUS CATS (S62311AX) monthly with 3 vials purchased on an unknown date from Walmart. The product was applied directly on the skin between the shoulder blades. Fleas were seen prior to product application. 14 Jul 2019*, 11 Aug 2019*, and 15 Sep 2019*: The monthly doses were applied. The pet owner continued to see fleas throughout. 1 Oct 2019: The owner is still noticing severe fleas. The cats are indoors only. The cats have not presented to the veterinary clinic. The pet owner gave Capstar on an unknown date. The cats' current condition is ongoing. There a total of 1 canines and 2 indoor felines in the household. The dog in the home is experiencing similar symptoms, see case 19US058521. No further medical information expected.
02-Oct-2019	UAE; 19US058630; PA; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 16.00 Year(s) **Weight:** 15 - 16 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	23-Sep-2019	27-Sep-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the pet owner reported the following event for Bailey, a 16 year old, spayed female, 15-16 pound, Shih Tzu/Poodle mix. 2016*: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (S60401AX) monthly seasonally. 23 Sep 2019: The most recent date of application. The product was applied directly on the skin between the shoulder blades. Fleas were not seen prior to product application.

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ED_005739D_00014391-00255

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						Route: Topical / Cutaneous **Was the product used ok?:** Yes					27 Sep 2019: The owner noticed 200-300 fleas. The dog has access to an outdoor area, it is unknown if there are trees on the property. The dog does go to the groomer, and was bathed on 27 Sep 2019 and 29 Sep 2019 with a pet shampoo. The dog's current condition is ongoing. This is the only pet in the household. No further medical information expected. UPDATE 28 Oct 2019: The owner is still seeing about 15-20 fleas on the pet. The pet owner did apply FRONTLINE GOLD again on 20 Oct 2019. No further medical information expected.
02-Oct-2019	UAE; 19US058634; NC; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 17.00 Month(s) **Weight:** 7 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (zzOff label use / Indication)	06-Sep-2019	18-Sep-2019*	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 02 Oct 2019, the pet owner reported the following event for Ellie a 7 pound, 1 year (11 Apr 2018), spayed female, Yorkshire Terrier. 06 Nov 2018*: The owner applied the contents of 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R61709AL) to the skin between the shoulder blades for the first time monthly. 06 Sep 2019: The owner applied a dose. 18 Sep 2019*: The owner noticed 5 live fleas on pet. 29 Sep 2019: The owner applied a dose. 02 Oct 2019: The owner reports still seeing 5 live fleas on pet. This is the only pet in the house. The owner bathes with Gold Medal Pet Oatmeal Shampoo every 2 to 3 weeks, it is unknown when the dog was last bathed. The pet is allowed in the backyard. The owner is not seeing any flea activity in the home. No further medical information expected.
02-Oct-2019	UAE; 19US058637; MD; U.S.A	**Species:** Canine **Breed:** Siberian Husky **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 54 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Apr-2019*	15-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy: On 2 Oct 2019, a pet owner reported the following event for Mischka, a 3 year old, 54 pound*, spayed female, Siberian Husky canine. 1 Jan 2017*: The dog started to receive FRONTLINE PLUS DOG 45-88LBS (S61603AX) between the shoulder blades monthly, year round. 1 Apr 2019*: The dog received FRONTLINE PLUS DOG 45-88LBS (S61603AX) between the shoulder blades . The pet owner applies flea prevention monthly year round. There are also 5 other dogs in the home that also receive a smaller dose of FRONTLINE PLUS (see case 19US058640) and one cat who receives FRONTLINE PLUS (see case 19US058616). 15 Apr 2019*: The owner discovered the dog had fleas. 1 Oct 2019*: The dog's recieved the most recent application of FRONTLIN PLUS. 2 Oct 2019*: The pet owner is continuing to see fleas on the dog. T.hey have not stopped seeing fleas all summer on the dogs. The other 5 dogs in the home have fleas as well and have access to a large back yard that is surrounded by foliage and trees. The owner reports there are always more fleas at the end of the month. The owner lives in a rural neighborhood and wildlife frequents the area. The owner has been purchasing the FRONTLINE PLUS from Ebay since the beginning of this year. It is unknown if the owner is seeing fleas in the home. No further medical information expected.
02-Oct-2019	UAE; 19US058640; MD; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 23.000 -	5	5	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	01-Jan-2017*	15-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy: On 2 Oct 2019, a pet owner reported the following event for 5 dogs, 1 to 5 years old, 23 to 25 pounds* in weight, spayed and neutered female and male, Small mixed breed canines. 1 Apr 2019*: The dogs started receiving FRONTLINE PLUS DOG 23-44LBS (S61602AX) between the shoulder blades with the last administration on 1 Oct 2019*. The pet owner applies flea prevention monthly year round and has been using this since

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		25.000 lbs*				**Route:** Topical / Cutaneous **Was the product used ok?:** Yes					2017* on the dogs. There is also 1 other dog in the home that also receives a different size of FRONTLINE PLUS (see case 19US058637) monthly and one cat who receives FRONTLINE PLUS (see case 19US058616) monthly. 15 Apr 2019*: The owner discovered the dogs had fleas. The other dog in the home has fleas as well and they all have access to a large back yard that is surrounded by foliage and trees. The owner reports there are always more fleas at the end of the month on all of the animals. The owner lives in a rural neighborhood and wildlife frequents the area. The owner has been purchasing the FRONTLINE PLUS from Ebay since the beginning of this year. The owner has not stopped seeing fleas all summer. It is unknown if the owner is seeing fleas in the home. No further medical information expected.
01-Oct-2019	UAE; 19US058648; NY; U.S.A	**Species:** Avian **Breed:** Timneh African Grey Parrot **Sex:** M **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** Environmental **Was the product used ok?:** Unknown to Company	01-Sep-2019*	03-Sep-2019*	2 Day(s)	D-B	Suspected Adverse Event: On 1 Oct 2019,the following event was reported to Safety Call International (SCI) by the pet owner for Maya, a unknown male, unknown weight, 15 year old*, African Grey Parrot. 26 Aug 2019* - 27 Aug 2019*: The pet began to vomit and act lethargic. 1 Sep 2019*: The pet owner appplied one vial of FRONTLINE PLUS DOG 45-88 LBS(F60809AX) to an unknown canine topically between the shoulder blades. The pet owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS(F60401AX) to each of the 2 unknown canines topically between the shoulder blades. 3 Sep 2019: The pet was seen by a veterinarian and hospitalized. During the hospitalization seizures developed and he was diagnosed with Bornavirus. Treatment has included anti-seizure medications and injectable anti-inflammatories. He has shown signs of improvement. The product was not applied directly to the bird. The bird lives with 3 dogs in the home who received the product. The bird does not interact or climb on the dogs, other then tease them with food. No further medical information expected.
02-Oct-2019	UAE; 19US058653; KY; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 91 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Jul-2019	16-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the owner reported the following event for Romeo, 11 years old, 91 pounds, neutered male, Retriever (Labrador, Black). 15 July 2019: The dog started on FRONTLINE PLUS on a monthly basis. 15 Sept 2019: The most recent vial of FRONTLINE PLUS DOG 89-132 LBS (S62904AX) was applied between the shoulder blades, by the pet owner. 16 Sept 2019*: The dog had fleas. 1 Oct 2019: The dog was bathed in a unknown pet shampoo. The owner was seeing flea activity in the home. The owner had an exterminator treat the home in July and August. The dog has access to a fenced in yard and goes on nightly walks in the neighborhood. No further medical information is expected.
02-Oct-2019	UAE; 19US058658; VA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	29-Sep-2019*	30-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, the owner reported the following event through the FRONLTINE UK facebook page, for 4 canines of unknown signalment. UNKNOWN: The owner applied FRONTLINE PLUS (lot unknown) Package unavailable, by an unknown method and for an unknown amount of time. UNKNOWN: Owner began seeing an unknown amount of fleas on all 4 dogs.

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ED_005739D_00014391-00257

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						Route: unknown **Was the product used ok?:** Unknown to Company					Owner stated the Frontline has worked in the past. No further information expected.
02-Oct-2019	UAE; 19US058662; TX; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Sep-2019	28-Sep-2019	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, a pet owner reported the following event for Hendricks, an 8 year old, 10 pound, neutered male Maltese/Miniature Poodle mix. 6 Jun 2019: The dog started receiving monthly applications of FRONTLINE PLUS DOG 5-22 LBS (S62405AX) topically between the shoulder blades in one spot for the first time. The owner purchased an 8 pack from Costco. No fleas were seen prior to application. 16 Sep 2019: The most recent application of FRONTLINE was applied. No fleas were seen. 28 Sep 2019: The dog went to grooming and the groomer found an unknown amount of live fleas on the dog's tail and inner thighs. There is no flea activity inside of the home. The dog goes to the groomer once a month. The back yard is fenced in and there are no decks or crawl spaces on the property. There are some bushes and a tree on the property. There are no other pets in the home. No further information expected.
02-Oct-2019	UAE; 19US058700; FL; U.S.A	**Species:** Feline **Breed:** Calico **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 10.63 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	01-Oct-2019	0 Day(s)	D-C	Suspected Adverse Event: On 2 Oct 2019, the pet owner reported the following event for Onyx, a 3 year old, 10.63 pound, spayed female, indoor-only, Calico feline. 1 Oct 2019: Around 3:00 PM, the reporter applied one vial of FRONTLINE PLUS CATS (FL+) (M41006AW) topically between Onyx's shoulder blades. It's possible that the feline has previously received FL+, but the reporter cannot recall. Immediately following product application, the feline seemed irritated and disoriented. Overall, she seemed a little off, but otherwise was fine for the rest of the day. The reporter could not further describe Onyx's symptoms. 2 Oct 2019: Around 8:00 AM, the reporter woke up to find the feline laying on the floor away from the chair she normally is always on in the morning as if she was trying to hide. When she walked over to Onyx, the cat didn't move or acknowledge her presence. Generally she seemed unresponsive despite the reporter trying to engage with her. When she picked Onyx up and placed her on the ground, she fell to the ground. An unknown time thereafter, she was taken to the emergency clinic where she remains hospitalized with the ongoing symptoms as well as gait ataxia. Unknown diagnostics are being performed and it's unknown if any treatment has been administered. The pet owner confirmed that Onyx could not have been exposed to any toxins in the home. There is a second cat in the home that experienced a similar event following FL+ application a year ago. Please see case 19US050789 for details. No further medical information expected.
02-Oct-2019	UAE; 19US058709; FL; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other	01-Oct-2018*	03-Oct-2018*	2 Day(s)	D-D	Suspected Adverse Event: On 2 Oct 2019, the pet owner reported the following event for an 8 year old, female, feline of further unknown signalment. Unknown dates: In 2018, one vial of FRONTLINE PLUS CATS (FL+) (lot unknown; package unavailable) was applied topically in an unknown location by the reporter. It's unknown if the patient has previously received FL+. Two days after product application, she

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ED_005739D_00014391-00258

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					became disoriented, was falling over, foaming at the mouth and was lethargic. Overall, her whole health took a decline. It took about 1.5 months for the feline to recover. The reporter would not provide any additional information regarding the event which he now suspects was caused by FL+. Another cat in the home recently received FL+ and is experiencing a similar adverse event. Please see case 19US058700 for details. No further medical information expected.
02-Oct-2019	UAE; 19US058725; MD; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Mixed **Age:** 1.50 Year(s) **Weight:** 8 - 18 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Sep-2019	30-Sep-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 October 20192019, the pet owner reported the following event for Smokey a 1.5 year old, 18 pound male domestic long hair feline and Lexi a 3.5 year old 8 pound female domestic short hair feline. Unknown 2018*: The pets began receiving monthly FRONTLINE PLUS CATS (Lot unknown) (package unavailable). Owner applied 1 vial topically between the shoulder blades. The pets are treated year round. 14 Sep 2019: The owner applied the monthly dose 30 Sep 2019: The owner noticed small amount of fleas on Lexi and a large amount of fleas on Smokey. The owner has not been noticing fleas off of the pets inside the home. There a total of 2 felines in the household. Lexi is indoor only and Smokey is indoor/outdoor. The yard is rural with wildlife. No further medical information expected.
02-Oct-2019	UAE; 19US058744; MD; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** F **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 52 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)	27-Sep-2019	28-Sep-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 2 Oct 2019, the owner reported the following event for Rose, 13 year old (2 Aug 2006), 52 pound, spayed female, Black Labrador Retreiver and Newfoundland mix canine. Unknown date: Fleas were noted on the pet. 27 Sept 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (F66904AX) was applied between the shoulder blades. 28 Sept 2019: The owner continued to find fleas on the pet. The owner also noticed the pet had dandruff localized at the application site. 2 Oct 2019: The issue is still ongoing. The pet received the product before on prior unknown dates and experienced the same issue with dandruff. No further medical information is expected. UPDATE 12 Nov 2019: After further review, added the product problem type AE on the product screen, per case type. No further medical information is expected.
02-Oct-2019	UAE; 19US058760; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Contraindication per label)	20-Sep-2019	25-Sep-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, a pet owner reported the following event for a feline of unknown signalment. Unknown Date: The cat has been on FRONTLINE PLUS CATS (lot unknown, package unavailable) monthly for an unknown amount of time year round. 20 Sep 2019: The most recent dose was applied, it is unknown if fleas were present. 25 Sep 2019: Owner applied another dose due to seeing fleas. 2 Oct 2019: The owner saw fleas, the cat goes outside. There is a dog in the house that is on Advantage 2. All further details unknown. No further medical information expected.

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ED_005739D_00014391-00259

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
02-Oct-2019	UAE; 19US058761; CA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** X **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 8 - 25 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	31-Jul-2019	30-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the owner reported the following event for 3, 5-10 years old, 8-25 pounds, neutered, Domestic Shorthair. 31 July 2019: The cats started on FRONTLINE PLUS on a monthly basis. 29 Sept 2019: The most recent vial of FRONTLINE PLUS CATS (S41004AW) was applied between the shoulder blades, by the pet owner. 30 Sept 2019*: The cats had fleas. The cats do not get bathed. The owner is not seeing any flea activity in the home. The cats are indoor/outdoor. There are 2 dogs in the household also using FRONTLINE PLUS reference case 19US059167. No further medical information is expected.
02-Oct-2019	UAE; 19US058764; PA; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 40 - 50 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	13-Sep-2019*	25-Sep-2019	12 Day(s)	D-C	Suspected Adverse Event: On 2 Oct 2019, the owner reported the following event for Chica, a 40-50 pound*, female neutered, 12 year old, Chihuahua Mix. 13 Sep 2019*: One vial of FRONTLINE PLUS DOG 23-44 LBS (H61901AL) was applied topically in one location in-between the shoulder blades by the pet owner. The owner purchased the product on or around the first September. 25 Sep 2019: The owner noticed skin irritation and hair loss on the pet's back to the tip of the pet's tail. The dog was presented to the clinic and treated with an unknown cream. 2 Oct 2019: The symptoms are still on going. The pet has used other topical products previously at an unknown date with no symptoms noted. No further information is expected.
02-Oct-2019	UAE; 19US058773; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 17.5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Jun-2019*	03-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the owner reported the following event for a, 17.5 pounds, feline (all other signalments unknown). June 2019: The cat started on FRONTLINE PLUS on a monthly basis. 1 Sept 2019: The cat was bathed in an unknown shampoo. 2 Sept 2019: The most recent vial of FRONTLINE PLUS CAT (S41003AW) was applied between the shoulder blades, by the pet owner. 3 Sept 2019*: The cat had fleas. The owner stated that flea activity is in the home. The cat is indoor only. The owner stated that fleas are resistant to the product. No further medical information is expected.
02-Oct-2019	UAE; 19US058798; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Jan-2019	29-Jan-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the owner reported the following event for 2 dogs a 120 pound Bernese Mountain Dog and 122 pound Shepherd. *29 Jan 2019: The dogs had fleas for a month or two and started FRONTLINE PLUS DOG 89-132 LBS topically between the shoulder blades for the first time. The dogs continued to be treated monthly for the past 9 months with the most recent application given 29 September 2019. There aren't any fleas in the home. The dog are bathed every few months with flea shampoo and is exposed to a fenced yard daily. The bigger dog has FAD. There is one other dog in the home treated with FL in a different weight category and has fleas , see case 19US059198. No further information available.

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ED_005739D_00014391-00260

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
02-Oct-2019	UAE; 19US058806; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	6	6	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Hartz Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Sep-2019	02-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the pet owner reported the following event for 2 Beagles, 2 Pekinese, and 2 Pomeranians of further unknown signalment. 1 Aug 2019, 1 Sept 2019, and 25 Sept 2019: The pet owner applied the last 3 doses of FRONTLINE PLUS DOG (unsubstantiated) (lot and expiration unknown, package unavailable) to each dog. The pet owner only uses seasonally starting on an unknown month. Jun 2019*: The pet owner started finding fleas on the dogs. 2 Oct 2019: The pet owner is still finding fleas on the dogs. There are 2 dogs who stay outside and the others are indoor/outdoor. There are fleas in the home. The home and the yard have been treated. Some of the dogs are bathed up to 1x week with Hartz fleas shampoo. There are 4 indoor cats who also have fleas, see case 19US058815. No further medical information expected.
02-Oct-2019	UAE; 19US058809; NY; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Dawn Dish soap; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Jul-2019*	02-Oct-2019*	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the pet owner reported the following event for 2 felines of unknown signalment. Unknown Date: The owner can not remember when the product was started. 14 Jul 2019*-14 Sep 2019: The pet owner applied one vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) topically between the shoulder blades. 25 Aug 2019*: The pet owner noticed fleas and bathed the pets in Dawn dish soap. 15 Sep 2019*: The pet owner continues to notice an unknown amount of fleas on the pet. The pets are indoor only and have no access outside. There are no other pets in the home. No further medical information expected.
02-Oct-2019	UAE; 19US058815; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Sep-2019	02-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the pet owner reported the following event for4 felines of further unknown signalment. 1 Aug 2019, 1 Sept 2019, and 25 Sept 2019: The pet owner applied the last 3 doses of FRONTLINE PLUS CATS (lot and expiration unknown, package unavailable) to each cat. The pet owner only uses seasonally starting on an unknown month. Jun 2019*: The pet owner started finding fleas on the cats. 2 Oct 2019: The pet owner is still finding fleas on the cats. The cats stay inside. There are fleas in the home. The home and the yard have been treated. The cats are not bathed. There are 6 dogs in the home who also have fleas, see case 19US058806. No further medical information expected.
02-Oct-2019	UAE; 19US058825; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	07-May-2019*	30-Sep-2019	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 02 Oct 2019, the pet owner reported the following event for 4 dogs of unknown signalment. 07 May 2019*: The owner applied the contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (unknown/ product unavailable) to the skin between the shoulder blades for the first time of the season. 07 Sep 2019: The owner applied a dose. 30 Sep 2019: Live fleas were noticed on the pet. 02 Oct 2019: The owner reports still seeing live fleas on the pets. All the dogs were bathed with unknown canine oatmeal shampoo. There are no other pets in the home and no previous flea concerns or medical issues. The dogs are allowed outside in the back yard. No fleas have been seen in the home. No further medical

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ED_005739D_00014391-00261

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					information expected.
02-Oct-2019	UAE; 19US058840; -; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** 8.50 Month(s) **Weight:** 6 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Oct-2019	02-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 2 Oct 2019 a pet owner called to report the following event in Cottonball, a 8.5 month old*, 6.0 pound*, female, Domestic Longhair feline with further unknown signalment. 2 Oct 2019: The owner applied FRONTLINE PLUS CATS (PT08971, invalid) to the cat in between the shoulder blades for the first time. The cat was able to lick some of it from her neck area and then ran around like she didn't like it. The cat has stopped running around now, is not licking anymore and has recovered. There is an unknown number of other cats in the home that have had FRONTLINE PLUS applied to them with no adverse reactions noted. No further medical information expected.
02-Oct-2019	UAE; 19US058861; -; U.S.A	**Species:** Canine **Breed:** English Bulldog **Sex:** M **Sex qualifier:** - **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	11-Sep-2019*	01-Oct-2019	20 Day(s)	D-C	Suspected Adverse Event and Lack of Efficacy: On 02 Oct 2019, the pet owner reported the following event for 2 English Bulldogs, intact males, all other signalment unknown. 11 Sep 2019*: The owner applied the contents of 1 vial of FRONTLINE PLUS DOG(product unsubstantiated) (lot unknown/ package unavailable) topically to an unknown location to each dog for the first time after seeing fleas. 01 Oct 20119: The owner checked the semen of each dog under a microscope and there were no live sperm. 02 Oct 2019: The owner is still seeing live fleas. There are 6 other dogs in a kennel environment that were not reported to have received the product. The dogs have free access to an outdoor run. Due to the nature of the caller, no other information was obtained. No further medical information expected.
02-Oct-2019	UAE; 19US058867; OH; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Mixed **Age:** - **Weight:** 12.000 - 22.000 lbs*	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Aug-2019	05-Aug-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the pet owner reported the following event for 3 canines of unknown signalment weighing between 12-22 pounds*. Oct 2016*: The pets began receiving monthly FRONTLINE PLUS DOG 5-22 LBS (Lot unknown) (package unavailable). Owner applied 1 vial per animal topically between the shoulder blades. The pets are treated year round. 4 Aug 2019: Owner applied the monthly dose, FRONTLINE PLUS DOG 5-22 LBS (S60401) from an 8 pack bought at Sams. 5 Aug 2019*: The owner began seeing a small amount of fleas on the pets. 4 Sep 2019: Owner applied the monthly dose. The owner has been noticing fleas off of the pets inside the home . The yard is fenced. There a total of 6 canines in the household. See case 19US058881 and 19US061430. No further medical information expected.
02-Oct-2019	UAE; 19US058881; OH; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Mixed **Age:** - **Weight:** 23 - 44 lbs*	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	04-Aug-2019	05-Aug-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the pet owner reported the following event for 3 canines of unknown signalment weighing between 23-44 pounds*. Oct 2016*: The pets began receiving monthly FRONTLINE PLUS DOG 23-44 LBS (Lot unknown) (package unavailable). Owner applied 1 vial per animal topically between the shoulder blades. The pets are treated year round. 4 Aug 2019: Owner applied the monthly dose, FRONTLINE PLUS DOG 23-44 LBS (S60713) from an 8 pack bought at Sams. 5 Aug 2019*: The owner began seeing a small amount of fleas on

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ED_005739D_00014391-00262

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					the pets. 4 Sep 2019: Owner applied the monthly dose. 5 Sep 2019*: Owner is still seeing fleas. The owner has been noticing fleas off of the pets inside the home . The yard is fenced. It is unknown what treatment was given to the pet and if the pet has recovered. There a total of 6 canines in the household. See case 19US058867 and 19US061430. No further medical information expected.
02-Oct-2019	UAE; 19US058882; VA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	10	10	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	01-Jul-2019*	02-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the owner reported the following event for 10 canine(all other signalments unknown). July 2019: The dogs started on FRONTLINE PLUS. This was the first dose of the product. Fleas were seen before application. 1 Oct 2019: The most recent vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, reported not queried) was applied between the shoulder blades, by the pet owner. 2 Oct 2019: The dogs had a moderate amount of fleas. The dogs are bathed once a month in an unknown flea shampoo. The owner is not seeing any flea activity in the household. The owner treated the home and the yard with an unknown treatment. The dogs have access to a fenced in yard for bathroom breaks. No further medical information is expected. UPDATE 3 Oct 2019: Per pet owner, started using FRONTLINE PLUS in Jul 2019* monthly.
03-Oct-2019	UAE; 19US058891; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 3 - 12 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	26-Sep-2019*	27-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Oct 2019, the owner reported the following event for two cats, approx. 3 and 12 pounds (all other signalments unknown). Unknown date: 1 cat started on monthly doses of FRONTLINE PLUS CATS (S40601AX) topically, between the shoulder blades, on a year round basis, by the owner. Aug 2019*: New kitten arrived in the home with fleas. 26 Sep 2019*: Both cats received a dose of FRONTLINE. This was the kitten's first dose of Frontline. 27 Sep 2019*: The owner continued to see fleas on the cats. The owner is not seeing fleas in the home. The owner treated with home with an unknown flea spray. The cats are strictly indoor. No further medical information expected.
03-Oct-2019	UAE; 19US058893; PA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Month(s) **Weight:** Unknown	2	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** FIPRONIL 9.8% / S-METHOPRENE 11.8% / PYRIPROXYFEN 0.25% TOPICAL SOLUTION; **Route:** Topical / Cutaneous	13-Jun-2019	13-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 03 Oct 2019, animal owner reported the following event for a 5 month old, neutered male cat. 13 Jun 2019: The pet owner adopted the kitten. The pet owner took the kitten to the vet for an exam. The kitten had fleas and the vet tech applied FRONTLINE SPRAY (Lot unknown/ package unavaiable) at an unknown dose. The pet owner purchased 4 doses of FRONTLINE GOLD FOR CATS. 23 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE GOLD FOR CATS (Lot unknown/ package unavailable) topically for the first time due to continuing seeing several live fleas. 08 Jul 2019: A dose was applied and the pet owner continued to see fleas. 07 Aug 2019: A dose was applied and the pet owner continued to see fleas. 07 Sep 2019: A dose was applied and the pet owner continued to

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ED_005739D_00014391-00263

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					see fleas. 30 Sep 2019: The pet owner saw live fleas on the cat. There is one other cat in the home with no issues. The pet owner has not bathed the cat. Both cats are indoor only. The enviroment has not been treated. No further information expected.
03-Oct-2019	UAE; 19US058930; CT; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Sep-2019	22-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 3 Oct 2019, the pet owner reported the following event for 3 felines of unknown signalment. Feb 2018*: The pet owner found fleas on the cats and then started applying FRONLTINE PLUS CATS (S41003AW) to each of the cats and treated with Capstar. The fleas were gone. 4 Jul 2019, 4 Aug 2019, and 4 Sept 2019: The pet owner applied the last three doses of FRONLTINE. 22 Aug 2019*: The pet owner started finding fleas again. The cats were treated with Capstar and the home has been treated. The cats do not go outside but there are feral cats outside. The cats are not bathed. There are no other pets in the home. FRONTLINE is usually applied year round, but was not applied for several months prior to Feb 2019*. No further medical information expected.
03-Oct-2019	UAE; 19US058943; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jan-2017*	15-Mar-2018*	12 Day(s)	D-A	Suspected Adverse Event: On 3 Oct 2019 a pet owner reported the following event for Blackie, a male feline of unknown signalment. Unknown Date: Cat started receiving FRONTLINE PLUS CATS (lot and exp unknown, package unavailable) on an unknown irrgeular schedule. Mar 2018*: Cat died from pancreatitis. The owner mentioned the death in passing, while calling to ask about the product expiration date and noted she does not feel the cat's death is related to FRONTLINe use. No further details were given. No further medical information expected.
03-Oct-2019	UAE; 19US058958; PA; U.S.A	**Species:** Canine **Breed:** Rottweiler **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 110 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Sep-2019	03-Oct-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Oct 2019 the pet owner reported the following event for a 110 pound Rottweiler of unknown signalment. Unknown Date: Started on FRONTLINE PLUS DOG 89-132 LBS (lot number unknown, package unavailable), 1 vial topically, in between the shoulder blades, once monthly. 29 Sep 2019: The most recent dose was applied. The pet owner stated another dog with fleas had stayed in the home approximately 1 month prior. He further stated that he had started seeing a small amount of fleas on his Rottweiler and inside the home approximately 2 weeks prior to the most recent application. 3 Oct 2019: Currently, the pet owner is still seeing a small amount of fleas on the canine. The canine spends the majority of the time inside the home with access to an outside lawn. There is one other canine in the household that is on Advantix that is also exhibiting fleas . No further medical information is expected.
03-Oct-2019	UAE; 19US058983; OH; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	19-Jul-2019*	20-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Oct 2019, the owner reported the following event for a canine (all other signalments unknown). July 2019: The dog started on FRONTLINE PLUS on monthly basis.

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ED_005739D_00014391-00264

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					19 Sept 2019: The most recent vial of FRONTLINE PLUS DOG 5-22 LBS (S60401AX) was applied between the shoulder blades, by the pet owner. 20 Sept 2019*: The dog had a large amount of fleas. The dog does not get bathed. It is unknown if flea activity is in the household. The dog has access to an unknown area for bathroom breaks. It is unknown if fleas were seen before starting on the product. No further medical information is expected.
03-Oct-2019	UAE; 19US058986; MD; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2019*	03-Oct-2019*	9 Month(s)	D-A	Suspected Adverse Event: On 3 Oct 2019, the pet owner called and reported the following for a feline of unknown signalment. Unknown date: Pet owner applied FRONTLINE (unsubstantiated) (lot unknown, reporter refused). An unknown volume per animal via an unknown route at an unknown location. 3 Oct 2019*: The pet owner reports the cat has passed. It is unknown if they presented to a veterinary clinic. It is unknown if any treatments had been administered. This is the extent of information known as caller refused to report. This event was mentioned while reporting a suspected lack of efficacy case for her dog (see case 19US053716). No further medical information expected.
03-Oct-2019	UAE; 19US059019; NC; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 65 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** dog shampoo/Dawn; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Aug-2019*	05-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 3 Oct 2019, the pet owner reported the following event for China, a 5 year old 65 pound female spayed Pit Bull. 6 Sept 2019, 20 Sept 2019, and 2 Oct 2019: Last doses of FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown, package unavailable) applied to the dog. Prior the dog has been receiving FRONTLINE monthly year round for an unknown number of years. 5 Sept 2019*: The pet owner started seeing fleas on the dog. 3 Oct 2019: The pet owner is still seeing fleas. The dog was treated with Nitenpryn. There are no other dogs in the home. The dog goes stays in a pen outside part of the day, which is treated. There are fleas in the home and the home has been treated. The dog is bathed 1x month with a dog shampoo or Dawn. No further medical information expected.
03-Oct-2019	UAE; 19US059023; VA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	01-Aug-2019*	10-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 03 Oct 2019, the pet owner called to report the following event for 3 cats of unknown signalment. 01 Jun 2019*: The owner applied the contents of 1 vial of FRONTLINE PLUS CATS (lot unknown/ package unavailable) to the skin between the shoulder blades on each cat for the first time monthly. 01 Aug 2019*: The owner applied a dose. 10 Aug 2019*: The owner noticed the cats itching and an unknown amount of live fleas on the cats. 15 Aug 2019*: The owner applied a dose every 2 weeks. 01 Oct 2019*: The owner applied a dose. 03 Oct 2019: The owner reports still seeing unknown amount of fleas. There are no other pets in the home. The cats are indoors only. No baths have been given. The owner reports to feral cats coming in and out of her yard. There are fleas seen in the home. No further medical information available.

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ED_005739D_00014391-00265

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
03-Oct-2019	UAE; 19US059034; GA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 5 - 50 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	05-May-2019*	06-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Oct 2019, the owner reported the following event for 3, 5-50 pounds, canines (all other signalments unknown). 2019: The dogs started on FRONTLINE PLUS early in the year on a monthly basis. 5 Sept 2019: The most recent vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) was applied between the shoulder blades, by the pet owner. 6 Sept 2019*: The dogs had a large amount of fleas. The dogs get bathed in an unknown shampoo. The owner is not seeing any flea activity in the home. The dogs have access to an unknown area for bathroom breaks. No further medical information is expected.
03-Oct-2019	UAE; 19US059038; IN; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** X **Sex qualifier:** Mixed **Age:** 12.00 Year(s) **Weight:** 3 - 9 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Sep-2019	02-Oct-2019	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Oct 2019, the owner reported the following event for 2 unknown Maltese, both 12 years old, between 3-9 pounds, all other signalment unknown. 17 Sep 2019: One vial of the FRONTLINE PLUS DOG 5-22 LBS (S61902AL) was applied topically between the shoulder blades. The owner purchased 2- 3 packs online at an unknown date for both dogs. 2 Oct 2019: The owner noticed a large amount of fleas on both dogs. The dogs are indoor mostly and use potty pads within the home. The dogs go outside in a fenced in yard once in the afternoons. The owner has not noticed wildlife in the area. Fleas have been seen within the home and the owner has treated the inside of the home. The pet has been receiving the FRONTLINE PLUS DOG 5-22 LBS year round for years per owner. This is the first time she has noticed fleas on the dogs. 3 Oct 2019: The dogs both have fleas. No further information expected.
03-Oct-2019	UAE; 19US059083; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	20-Sep-2019	03-Oct-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Oct 2019, a pet owner reported the following event for a feline of unknown signalment. 20 Sep 2019: The owner applied FRONTLINE PLUS CATS (lot unknown, package unavailable) and it is unknown if the cat had fleas or if this was the first dose. 3 Oct 2019: The owner saw fleas. It is unknown if the cat goes outside. All further details are unknown. No further medical information expected.
03-Oct-2019	UAE; 19US059084; WA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL 9.8% / S-METHOPRENE 11.8% /	15-Jun-2019*	03-Oct-2019	3 Month(s) 2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 03 Oct 2019, the pet owner reported the following event for 2 cats of unknown signalment. 15 May 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (lot unknown/ package unavailable) to the skin between the shoulder blades for the first time. Application was after seeing 2 live fleas on the cats. 15 Jun 2019*: A dose was applied. The same quantity of live fleas were still being seen on the cats. 15 Jul 2019*: The owner switched to FRONTLINE GOLD FOR CATS (lot unknown/ package unavailable) for the first time monthly.

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ED_005739D_00014391-00266

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						PYRIPROXYFEN 0.25% TOPICAL SOLUTION; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					15 Sep 2019*: A dose was applied. 03 Oct 2019: The owner reported the same amount of live fleas are still being seen. These are the only pets in the home. The cats are indoors/ outdoors. The cats have not been bathed. No fleas have been seen inside the home. No further medical information expected.
03-Oct-2019	UAE; 19US059104; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	01-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: 03 Oct 2019: An owner reported the following event in an unknown cat of unknown further signalment. 01 Sep 2019: The owner administered one FRONTLINE PLUS CATS (lot unknown, package unavailable) topically at the base of the skull for the first time. No fleas were seen at the time of application but flea dirt was seen. 01 Oct 2019: The owner administered one dose topically at the base of the skull for the second time. No fleas were seen at the time of application but flea dirt was seen. 03 Oct 2019: The owner is still seeing flea dirt when combing the cat. The cat is indoor-outdoor in an unknown environment. There are no other animals in the home. The status of the cat is unknown. No further medical information expected
03-Oct-2019	UAE; 19US059126; NC; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** - **Weight:** 36 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Sep-2019	03-Oct-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Oct 2019, the pet owner reported the following event for Fiba, a 36 pound, female spayed, medium crossbred canine. 15 Sep 2019: Bath in unknown pet shampoo. 25 Sep 2019: 1 vial of FRONTLINE PLUS DOG 23-44 LBS(T60109AX) was applied to the dog in one area between the shoulder blades. Since the application the owner has seen 5-10 fleas on the dog daily. 3 Oct 2019: There are 5-10 fleas on the dog. The dog goes out for potty breaks and recreation in wooded area. There are no fleas in the home. The owner has been treating with FRONTLINE monthly and yearound No further information.
03-Oct-2019	UAE; 19US059136; PA; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** F **Sex qualifier:** - **Age:** 20.00 Month(s) **Weight:** 43.4 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** RECOMBITEK LYME - 2126.R0; AFOXOLANER 68 MG CHEWABLE TABLETS; FIPRONIL 9.8% / S-METHOPRENE 8.8% / PYRIPROXYFEN 0.25%	03-Apr-2018	30-Sep-2019	18 Month(s)	D-C	Suspected Lack of Efficacy Claim: On 3 Oct 2019, a clinic staff member reported the following event for Kali, a 20 month old (born 29 Jan 2018), 43.4 pound, intact female Anatolian Shepherd. She received a RECOMBITEK LYME, 1 ml, SC, in the left rear leg on 21 Apr 2018 (Lot and Expiration Unknown, Package Unavailable), in an unknown location on 12 May 2018 (Lot and Expiration Unknown, Package Unavailable), and in the left rear leg on 20 Dec 2018 (42228, 9 Jul 2020). 30 Sep 2019: The dog was diagnosed Lyme antigen positive via a routine Snap 4 DX. A Quant C6 has not been performed. The dog is asymptomatic and no treatment has been initiated. The dog has received NEXGARD (68 MG) (Lot and Expiration Unknown, Package Unavailable) in the past on unknown dates with the following purchase history: 1 dose on 12 May 2018, 3 doses on 6 Oct 2018, and 3 doses on 20 Dec 2018. No further medical information at this time. UPDATE 8 Nov 2019: per medical record received on 28 Oct 2019: The pet is an Australian Shepherd.

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ED_005739D_00014391-00267

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						TOPICAL SOLUTION; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					3 Apr 2018: 1 dose of FRONTLINE PLUS DOG 23-44LBS (product unsubstantiated) was applied to the pet. 20 Dec 2018: 1 dose of FRONTLINE GOLD DOG 23-44 LBS (lot unknown) was applied to the pet. 28 Oct 2019: A Quant C6 test revealed a result of 42 (0-30). The pet was treated with doxycycline. No further medical information expected.
03-Oct-2019	UAE; 19US059139; MI; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** - **Age:** 11.00 Year(s) **Weight:** 10.8 lbs	2	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Albuterol; Unknown steroid injection; Dawn dish soap; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019	02-Oct-2019	1 Day(s)	D-A	Suspected Adverse Event: On 03 Oct 2019, the pet owner reported the following event for Pepper, 11 year (11 Aug 2008), 10.8 pound, intact male, Chihuahua. 01 Apr 2019*: Started monthly application of FRONTLINE PLUS DOG 5-22 LBS (S61902AL) topically to an unknown location for the first time. 01 Oct 2019: The owner applied a dose. 02 Oct 2019: The dog showed signs of lethargy, heavy breathing, inappetence. 03 Oct 2019: The pet was taken to the vet and had unknown treatment. The veterinarian recommended bathing the dog with Dawn. There is one other dog in the home also exposed to the product from this packaging and not showing any adverse signs. The dog does have congestive heart failure. The dog has used this product in the past with no issues. No further information available at this time. UPDATE 04 Oct 2019: The owner reports Pepper is feeling better today after 2 Dawn dish soap baths. The vet had treated the dog with an unknown steroid shot and Albuterol on 03 Oct 2019. FRONTLINE PLUS DOG is used seasonally and started 01 Jun 2019*. UPDATE 07 Oct 2019: Email received from pet owner on 05 Oct 2019, the pet owner noted that the pet's breathing is getting worse and is now vomiting. UPDATE 7 Oct 2019: Pet owner called and stated that pet seems to be doing better, still not completely normal, is eating and drinking okay now. UPDATE 04 Nov 2019: The owner reported on 01 Nov 2019, the pet was euthanized for unknown medical reasons. It is unknown if diagnostics were performed. No further medical information expected.
03-Oct-2019	UAE; 19US059149; OH; U.S.A	**Species:** Canine **Breed:** Schnauzer **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 25 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Jul-2019	15-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 03 Oct 2019, animal owner reported the following event for Rowdy, a 8 year old, 25 pound, neutered male, Schnauzer. 30 Mar 2019: Started monthly FRONTLINE PLUS DOG 23-44 LBS (M61511AL) topically between the shoulderblades. 30 Jul 2019: A dose was applied. *15 Aug 2019: The pet owner noticed * 5-10 live fleas on the dog. 30 Aug 2019: A dose was applied. 01 Sep 2019: The pet owner saw live fleas on the dog and now the dog is severaly itching and digging at his skin. The dog began puilling hair out. There is one other dog in the home who is currently on Advantage and a cat in the home currently on FRONTLINE GOLD CATS. Both house mates are not have any issues. The dog has not been seen by a vet and has not been bathed. No further information expected.

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ED_005739D_00014391-00268

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
03-Oct-2019	UAE; 19US059166; OR; U.S.A	**Species:** Canine **Breed:** Pekingese **Sex:** X **Sex qualifier:** Mixed **Age:** 9.00 Year(s) **Weight:** 10 - 11 lbs	5	5	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	03-Jul-2019	03-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Oct 2019 the pet owner called in the following event for 5 Pekingese dogs of unknown mixed sex, 10 to 11 pounds* and from 9 years to 15 years. 3 Jul 2019: The pet owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable) topically between the shoulder blades for the first time to each pet. Aug 2019: No dose of FRONTLINE PLUS was not given to the dogs. 3 Sep 2019: The pet owner noticed that the dogs were scratching. the owner applied FRONTLINE PLUS to all the dogs. 3 Oct 2019: The dogs continued to scratch, the pet owner is unsure if the dogs have fleas due to a thick hair coat. The dogs have access to a grass yard where urban wildlife and stray cats are present. The dogs are bathed every 4 to 6 weeks with an unknown pet approved shampoo. the pet owner does not see fleas in the home. The dogs were in good health prior to application and have no history of reactions. No further medical information expected.
02-Oct-2019	UAE; 19US059167; CA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 6 - 12 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	31-Jul-2019	30-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the owner reported the following event for 2, 10-12 years old, 6-12 pounds, neutered, Canines. 31 July 2019: The dogs started on FRONTLINE PLUS on a monthly basis. 28 Sept 2019: The dogs were bathed in an unknown shampoo. 29 Sept 2019: The most recent vial of FRONTLINE PLUS DOG 5-22 LBS (S60301AL) was applied between the shoulder blades, by the pet owner. 30 Sept 2019*: The dogs had fleas. The owner is not seeing any flea activity in the home. The dogs have access to an unknown area for bathroom breaks. There are 3 cats in the household also using FRONTLINE PLUS reference case 19US058761. No further medical information is expected.
04-Oct-2019	UAE; 19US059182; IA; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 8 lbs*	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn dish soap; Vaccines, unknown; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Sep-2019	01-Oct-2019*	9 Day(s)	D-D	Suspected Adverse Event: On 4 Oct 2019, reported the following event for a Dachshund, 7 month* old, 8 pound*, unknown female and Chihuahua, 1 year old*, 8 pound*, unknown female. 22 Sep 2019: The pet owner brought the pets to the veterinarian for their annual unknown vaccines. The pet owner washed the dogs in Dawn dish soap and let them dry naturally. The pet owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS (S61902) topically between the shoulder blades for the first time. 1 Oct 2019*: The dogs started to itch, no fleas are seen on the pets or in the home. The pets have access to a grass yard, where urban wildlife and stray cats are present. There is no dry skin or scabs present on the pets skin. There were no fleas seen on the pets prior to application. The pets were in good health prior to the application and have no history of reactions. No further medical information expected.
04-Oct-2019	UAE; 19US059188; MD; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** X **Sex qualifier:** Neutered	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other	24-Sep-2019	29-Sep-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 04 Oct 2019, the pet owner reported the following event for 3 felines, mixed sex, neutered, Domestic Shorthair, all other signalments unknown. 24 Jul 2019: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (T40109AW) to the skin between the shoulder blades for the first time monthly. No fleas were seen at the time of application.

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ED_005739D_00014391-00269

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - **Weight:** Unknown				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					24 Sep 2019: A dose was applied. 29 Sep 2019*: The owner noticed all the cats scratching and live fleas on the them. 04 Oct 2019: The owner reports still seeing live fleas on the cats. There are no other animals in the home. The cats are indoor/ outdoor. The owner does see feral cats, racoons, and opposums outside. No baths have been given. No fleas have been seen inside the home. The owner is vacuuming and washing bedding. No further medical information expected.
02-Oct-2019	UAE; 19US059198; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 70 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Jan-2019	29-Jan-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 2 Oct 2019, the owner reported the following event for a 70 pound dog. *29 Jan 2019: The dog had fleas for a month or two and started FRONTLINE PLUS DOG 45-88 LBS (lot and expiration date unknown) topically between the shoulder blades for the first time. The dog continued to be treated monthly for the past 9 months with the most recent application given 29 September 2019. There aren't any fleas in the home. The dog is bathed every few months with flea shampoo and doesn't have skin issues. The dog is exposed to a fenced in yard. There is one other dog in the home treated with FL in a different weight category and has fleas, see case 19US058798. No further information available.
04-Oct-2019	UAE; 19US059224; IL; U.S.A	**Species:** Feline **Breed:** Feline various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** Unknown	8	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL SPRAY; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019	02-Oct-2019	1 Day(s)	D-D	Suspected Adverse Event: On 4 Oct 2019, the pet owner reported the following event for 2 cats, 10 year old, with remaining signalment unknown. 1 Oct 2019: The cats received one vial of FRONTLINE PLUS CATS (M41310). 2 Oct 2019: The cats received a spray of FRONTLINE SPRAY (P04401A). That evening the cats began to meow a lot and laying in owner's bed a lot. The cats did not present to the clinic, and the owner did not bathe the cats. The cats conditions are ongoing. There are six other cats in the home, who also received the FRONTLINE PLUS CATS and FRONTLINE SPRAY with no adverse events. No further medical information expected.
04-Oct-2019	UAE; 19US059236; -; U.S.A	**Species:** Canine **Breed:** Siberian Husky **Sex:** M **Sex qualifier:** - **Age:** 3.00 Year(s) **Weight:** 45 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	03-Sep-2019	04-Oct-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 04 Oct 2019 an owner reported the following event in Mika, a 3-year-old, 45 pound, intact, male, Siberian Husky. 03 Jun 2019: The owner administered one FRONTLINE PLUS DOGS 45-88 LBS (S61211AL) topically in-between the shoulders for the first time. No fleas were seen at the time of application. 03 Jul 3019: The owner administered one dose topically in-between the shoulders for the second time. No fleas were seen at the time of application. 15 Jul 2019: The owner saw 6 fleas on the dog. 03 Aug 2019: The owner administered one dose topically in-between the shoulders for the third time. 4 fleas were seen at the time of application. 03 Sep 2019: The owner administered one dose topically in-between the shoulders for the fourth time. 3 fleas were seen at the time of application. 04 Oct 2019: The owner is still seeing an unknown amount of fleas. The dog is indoor-outdoor in an unknown environment. There is one other dog in the home in a smaller weight range. The

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ED_005739D_00014391-00270

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											status of the dog is unknown. No further medical information expected.
04-Oct-2019	UAE; 19US059237; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	19-Aug-2017*	19-Sep-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019, the owner reported the following event for a canine with unknown signalment. 2017*: The dog started monthly on FRONTLINE PLUS DOG 45-88 LBS (Lot Unknown, Package Unavailable) topically in between the shoulder blades. 19 Sep 2019: The pet was shaved and the owner noticed a moderate amount of fleas on the dog. One dose of FRONTLINE was given topically in between the shoulder blades. Capstar was also given. 1 Oct 2019: The owner was still seeing fleas so she bathed the pet in Dawn dish soap. 3 Oct 2019: Another dose of FRONTLINE was applied. 4 Oct 2019: The owner reports still seeing fleas on the dog. The dog is considered an outdoor dog that lives outdoors. The owner also mentioned that they live near the woods. There were no fleas noticed prior to product use. The pet does get baths with a sensitive skin shampoo and Dawn dish soap as needed due to fleas. The dog does not have a history of dry skin issues, however he does have a history of sensitive skin. There are 2 other indoor/outdoor cats in the home that are also on FRONTLINE FOR CATS (lot unknown) that do not have fleas. The owner has been treating monthly with FRONTLINE since 2017*. No further information at this time.
01-Oct-2019	UAE; 19US059242; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	30-Sep-2019*	01-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Oct 2019, a pet owner reported the following event for a feline of unknown signalment. Unknown Date: The cat received an unknown amount of FRONTLINE PLUS CATS (Lot Unknown, Package Unavailable) in an unknown manner. It is unknown if this was the first application or if the pet owner was seeing fleas prior. 1 Oct 2019*: The pet owner was seeing an unknown amount of live fleas on the cat. It is unknown if this cat is indoor only. It is unknown if the owner is seeing any flea activity inside the home. It is unknown if the cat receives baths or has skin issues. There was one other cat that the owner had brought inside the home and that cat had fleas. That cat is no longer with the owner. No further information expected.
04-Oct-2019	UAE; 19US059243; MI; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 62 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Sep-2016	03-Oct-2019	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019 the pet owner reported the following event for Juniper a 4 year old*, 62 pound*, spayed female, Golden Retriever. 2016* - 10 Aug 2019: The pet owner applied one vial of FRONTLINE PLUS DOG 45-88 LBS (S61810AX) topically between the shoulder blades monthly, year round. 10 Sep 2019: The pet owner applied the product topically between the shoulder blades. 3 Oct 2019: The pet owner noticed 3 ticks fully engorged on the pets body. The pet owner removed the live ticks. It is unknown how long the ticks were on the pet. The pets environment is unknown. The pet is bathed on a monthly basis with an unknown pet approved shampoo. No further medical information expected.
04-Oct-2019	UAE; 19US059246; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair	1	1	0	**Product used:** FIPRONIL 10%/S	21-Sep-2019	04-Oct-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 04 Oct 2019, the pet owner called to report the following event for Caesar, 6.1 pound, 5 month, neutered male, Domestic Shorthair.

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ED_005739D_00014391-00271

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		(Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Month(s) **Weight:** 6.1 lbs				METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					01 Aug 2019*: The owner briefly brought in an outdoor cat. 21 Sep 2019: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (S41307AW) to the skin on the side of the cat for the first time after seeing the scratching. 04 Oct 2019: The owner found 2 live fleas on the cat. This is the only pet in the home. The cat is indoors only, but has gotten out 2 times. No bath has been given. No fleas have been seen inside the home. No further medical information expected.
04-Oct-2019	UAE; 19US059258; IN; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** X **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 12 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Jul-2019	01-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019 the owner reported the following event for Bo, a 9 years old*, 12 pound*, neutered male, Domestic Medium Hair and Augie, a 8 year old*, 12 pound*, spayed female, Domestic Medium Hair. 15 Jul 2019: The owner applied one vial of FRONTLINE PLUS CATS (S40603AW) topically between the shoulder blades for the first time. No fleas are seen prior to the application of FRONTLINE PLUS. 1 Aug 2019*: The owner noticed a few fleas on the pet. 15 Aug 2019 and 15 Sep 2019: The pet owner applies the product and continues to see fleas on the pets. 4 Oct 2019: The pet owner is continuing to see fleas on the pets. The pet owner notices about 5 or 6 fleas* on her when the pets are around. The pets have access outside to a grass yard, where stray dogs, cats and urban wildlife are present. There are no other pets in the home. The pets are not bathed. The pets were in good condition prior to application, and have no history of reactions. No further medical information expected.
04-Oct-2019	UAE; 19US059280; WV; U.S.A	**Species:** Feline **Breed:** Himalayan **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 12.5 lbs	6	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Sep-2018*	01-Oct-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019, the pet owner reported the following issue for Puff, a 4 year old, 12.5 pound*, spayed female Himalayan. 15 Sep 2019*: The pet owner applied 1 dose of FRONTLINE PLUS CATS (lot unknown) (package unavailable), between the shoulder blades, in one spot, on the cat. There are 5 other cats in the home that also received 1 dose of FRONTLINE PLUS CATS. They are all strictly inside cats. The pet owner feeds 3 homeless outside cats in her backyard, away from her home. 1 Oct 2019: Puff escaped outdoors and the pet owner took the cat to the vet, because she was scratching. The vet noticed that the cat was covered in fleas. 2 Oct 2019: The pet owner bathed the cat in Dawn Dish soap. She is noticing a large amount of fleas on the cat. There are no fleas in the home and the pet owner has not noticed fleas on herself. The issue is still ongoing. The cat has been on FRONTLINE PLUS CATS monthly, year round for an unknown amount of years. The owner will discontinue use of FRONTLINE PLUS CATS. No further medical information expected.
04-Oct-2019	UAE; 19US059288; TX; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON	15-Sep-2019	16-Sep-2019	1 Day(s)	D-D	Suspected Adverse Event: On 4 Oct 2019, the pet owner reported the following event for Casper, a 12 year old 12 pound male neutered Domestic Mediumhair. 15 Sept 2019: The pet owner applied a dose of FRONTLINE PLUS CATS (S40210BW) between the shoulder blades.

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		Sex qualifier: Neutered **Age:** 12.00 Year(s) **Weight:** 12 lbs				**Other products used:** no other products **Route:** SC-subcutaneous **Was the product used ok?:** Yes					16 Sept 2019: The cat had hair loss down the spine almost to the tail with small lesions. The cat has also been more clingly. The pet owner applied unknown antibiotic ointment. 28 Sept 2019*: The cat recovered. The cat has been receiving the FRONTLINE for an unknown number of years. Case was reported with case 19US059292. No further medical information expected.
04-Oct-2019	UAE; 19US059290; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 85 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Sep-2019	03-Oct-2019	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019 a pet owner reported the following event for an 85 pound, male canine of unknown other signalment. 9 Sep 2019: Owner applied FRONTLINE PLUS DOG 45-88 LBS (S61810) to the skin between the animal's shoulder blades. 3 Oct 2019: Owner noticed 2 fleas on the dog. Owner has not seen any fleas in the home, but did see one on the deck. Approximately 3 weeks ago the owner had two dogs in a kennel on her deck that had fleas that she was pet sitting. Owner treated the deck with pesticide 2 weeks ago. Dog lives inside, but does go outside in a fenced yard where she has seen wildlife. Owner is unable to touch the dog on a regular basis due to aggression, so the dog is not bathed. The owner has been using FRONTLINE on the dog monthly for 3 years and has never seen fleas. There are no other animals in the home. No further medical information expected.
04-Oct-2019	UAE; 19US059292; TX; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Sep-2019	16-Sep-2019	1 Day(s)	D-D	Suspected Adverse Event: On 4 Oct 2019, the pet owner reported the following event for Kompact Kitty, an 8 year old 8 pound female spayed Domestic Shorthair. 15 Sept 2019: The pet owner applied a dose of FRONTLINE PLUS CATS (S40210BW) between the shoulder blades. 16 Sept 2019: The cat had a round spot of hair lost at the application site and she was hiding and acting depressed. The cat's status was the same at the time of the phone call. The cat has been receiving the FRONTLINE since 2014*. Case was reported with case 19US059288. No further medical information expected. No further medical information expected.
04-Oct-2019	UAE; 19US059293; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 2 - 9 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Sep-2019*	01-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019, the owner reported the following event for two cats, approx. 2 and 9 pounds (all other signalments unknown). Unknown date: 1 cat started on monthly doses of FRONTLINE PLUS CATS (S41006AW) topically between the shoulder blades, by the owner, on a year round basis. 29 Sep 2019*: The owner found a stray kitten and took it in. The kitten had fleas. 30 Sep 2019*: The owner applied FRONTLINE to both cats. 1 Oct 2019*: The owner was still seeing fleas on the cats. The owner is not seeing fleas in the home. The owner treated the home. The kitten is strictly indoor, but the older cat is indoor/outdoor and the owner lives in a mobile home park near the woods. No further medical information expected.
04-Oct-2019	UAE; 19US059300; TN; U.S.A	**Species:** Canine **Breed:** Canine (unknown)	1	1	0	**Product used:** FIPRONIL 10%/S	30-Sep-2019	01-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019, the pet owner reported the following event for Mabel, a 7 years old, 55 pound, female of unknown breed.

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		Sex: F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 55 lbs				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					Oct 2012*: The pet began receiving monthly FRONTLINE PLUS DOG (Lot unknown) (package unavailable), applied 1 vial topically between the shoulder blades. 30 Sep 2019*: Owner applied the monthly dose, FRONTLINE PLUS DOG 45-88 LBS (S62408AX). 1 Oct 2019: The owner noticed a small amount of fleas on the pet. The owner has not been noticing fleas off of the pet inside the home. There a total of 1 canine and 1 outdoor feline in the household. The yard is large and wooded. The feline is not treated. No further medical information expected.
04-Oct-2019	UAE; 19US059302; NJ; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.50 Year(s) **Weight:** 21 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	28-Sep-2019	03-Oct-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019, a pet owner reported the following event for Snoops, a 4.5 year old, 21 pound, neutered male Domestic Shorthair. 2016*: The cat began receiving monthly, year round applications of FRONTLINE PLUS CATS (R40110AW) topically between the shoulder blades in one spot. 13 Jul 2019 and 9 Aug 2019: The cat received 1 application of FRONTLINE. No fleas were seen. 4 Sep 2019: The most recent application of FRONTLINE was applied. 3 Oct 2019: The owner was brushing the cat and saw some flea dirt. 4 Oct 2019: The owner brushed the cat and saw more flea dirt and 2 small live fleas. The cat is indoor/outdoor and will roam to other yards. The outside yard is fenced in. There is no flea activity inside the home. The cat does not receive baths and there are no other pets. No further information expected.
04-Oct-2019	UAE; 19US059304; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	15-Apr-2019*	30-Jul-2019*	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 04 Oct 2019, the pet owner reported the following event for 2 canines of unknown signalments. 15 Apr 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 5-22 LBS (F60713AX) to the skin between the shoulder blades of each dog monthly for the first time of the season. 15 Jul 2019: The owner applied a dose. 30 Jul 2019*: The owner noticed an unknown amount of live fleas on 1 of the 2 dogs. 01 Aug 2019*: The owner applied a dose. 15 Aug 2019*: The owner applied a dose. 05 Sep 2019*: The owner continued to notice live fleas and applied a dose. 20 Sep 2019*: The owner rinsed the dogs with water then applied a dose. 04 Oct 2019: The owner reports continuing to see an unknown quantity of live fleas on one of the dogs. There are no other pets in the home. No prior skin issues were reported. The dogs are mostly indoors. The owner notes stray cats being in the neighborhood. No further medical information expected.
04-Oct-2019	UAE; 19US059308; MI; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Neutered **Age:** 11.50 Year(s) **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	20-Sep-2019	04-Oct-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019, the pet owner reported the following event for Clarence, an 11.5 year old 15 pound male neutered Shih Tzu/Poodle mix. Jul 2019*: The pet owner started applying monthly doses of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable) because the pet owner started seeing fleas on the dog the day before.

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						products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					4 Oct 2019: The pet owner is still finding fleas on the dog. There is another dog in the home who is also on FRONTLINE and has fleas. The dogs goes outside for short breaks. They are bathed every few months with a dog shampoo. There are no fleas in the home. Other dog's case is 19US059310. The pet owner has been using FRONTLINE seasonally since 2016*. No further medical information expected.
04-Oct-2019	UAE; 19US059310; MI; U.S.A	**Species:** Canine **Breed:** Spaniel **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 45 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Sep-2019	04-Oct-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019, the pet owner reported the following event for Jenny, a 6 year old 45 pound female spayed Spaniel mix. Jul 2019*: The pet owner started applying monthly doses of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) because the pet owner started seeing fleas on the dog the day before. 4 Oct 2019: The pet owner is still finding fleas on the dog. There is another dog in the home who is also on FRONTLINE and has fleas. The dogs goes outside for short breaks. They are bathed every few months with a dog shampoo. There are no fleas in the home. Other dog's case is 19US059308. The pet owner has been using FRONTLINE seasonally since 2016*. No further medical information expected.
04-Oct-2019	UAE; 19US059312; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 48 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	13-Aug-2019*	20-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019, the owner reported the following event for a 48 pound canine (all other signalments unknown). Unknown date: Started on monthly doses of FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown, package unavailable) topically between the shoulder blades, by the owner. 13 Aug 2019*: Another dose of FRONTLINE was applied. 20 Aug 2019*: The owner started seeing fleas on the dog. 13 Sep 2019*: Most recent dose of FRONTLINE was applied. The owner is still seeing a moderate amount of fleas on the dog. The owner is not seeing fleas in the home. All other information is unknown as the call was disconnected and attempts to reach out to the owner were unsuccessful. No further medical information expected.
04-Oct-2019	UAE; 19US059320; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown Pet Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	02-Oct-2019	04-Oct-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 04 Oct 2019, the pet owner reported the following event for a male canine of further unknown signalment. UNKNOWN DATE: The dog began receiving 1 full vial of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown, package unavailable) between the shoulder blades seasonally. 01 Oct 2019: The owner saw an unknown number of fleas on the dog. The dog was bathed with an unknown pet shampoo. 02 Oct 2019: The most recent dose of FRONTLINE was applied. 04 Oct 2019: The owner saw one flea on the dog. Further details not obtained due to call ending after all of callers' questions were answered. No further medical information expected.
04-Oct-2019	UAE; 19US059323; IL; U.S.A	**Species:** Canine **Breed:** Canine (unknown)	2	2	0	**Product used:** FIPRONIL 10%/S	05-Jul-2019*	04-Oct-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019 a pet owner reported the following event for 2 canines, one 60* pound female and one 75 pound male, other signalment unknown.

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ED_005739D_00014391-00275

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: X **Sex qualifier:** Unknown **Age:** - **Weight:** 60 - 75 lbs				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					5 Jun 2019 : Owner applied FRONTLINE PLUS DOG 60-75 LBS (S61810AX) to the skin between the animal's shoulder blades for the 1st dose of the season. Applied Jun 2019*, Jul 2019*, Aug 2019*, and 29 Sep 2019. Jul 2019*: Owner starting finding fleas on the dogs on and off. 4 Oct 2019: Owner found 2 fleas on the dog. There is a cat in the home who does not have fleas, lives inside and outside, and using FRONTLINE monthly since Jun 2019*. There is a 3 week old kitten that has fleas and is not on a product due to age. Fleas are biting the 3 year old daughter in the home. The dogs live inside, going outside in a fenced back yard, mostly mud and grass with one large tree. The owner sees wildlife in the yard. The owner is not bathing the cats or the dogs, no additional products used on them. Treated the yard and the home with an indoor and outdoor spray. Bathed the kitten in Dawn dish liquid and removed live fleas. The owner has been using the product seasonally for an unknown number of years. No further medical information expected.
04-Oct-2019	UAE; 19US059341; MS; U.S.A	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** M **Sex qualifier:** Neutered **Age:** 15.00 Year(s) **Weight:** 20 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Jul-2019	04-Oct-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019 the pet owner reported the following event for Rufas, a 15 year old (born 4 Apr 2004), 20 pound, neutered male Jack Russell Terrier. 23 Jul 2019: The pet started on FRONTLINE PLUS DOG 5-22 LBS (lot number unknown, package unavailable), 1 vial topically, in between the shoulder blades, once monthly. The pet owner noted a small amount of fleas on the canine and inside the home for an unknown amount of time at the time of application. 23 Sep 2019: The most recent dose was applied. 4 Oct 2019: The pet owner reports that the canine still has a small amount of fleas. Rufas spends the majority of the time inside the home with access to an outside lawn. There are no other pets in the household. No further medical information is expected.
04-Oct-2019	UAE; 19US059359; GA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 9 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	20-Sep-2019*	04-Oct-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019, the pet owner reported the following event for a 9 pound feline, with remaining signalment unknown. 20 Sep 2019*: The cat began receiving FRONTLINE PLUS CATS (lot unknown, reporter refused) 4 Oct 2019: Pet owner seeing fleas on the cat. It is unknown if they presented to a veterinary clinic. It is unknown if any treatments have been administered. Their current condition is unknown. It is unknown what environment the feline frequents. It is unknown if the owner bathes the feline. It is unknown if there are any other pets in the household. It is unknown if the cat has had FRONTLINE in the past. This is the extent of information known as caller refused to report. No further medical information expected.
04-Oct-2019	UAE; 19US059385; WV; U.S.A	**Species:** Feline **Breed:** Russian Blue **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 11 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical /	02-May-2019*	04-Oct-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019, the pet owner reported the following event for Boy, a 6 year old 11 pound male neutered Russian Blue. May 2019*: The pet owner started to apply monthly doses of FRONTLINE PLUS CATS (S40101BW). 4 Oct 2019: The pet owner found a flea on the cat. The cat goes outside sometimes. There are no other pets in the home. The cat is not bathed. It is unknown if there are fleas in the home. No further medical information expected.

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ED_005739D_00014391-00276

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** Yes					
04-Oct-2019	UAE; 19US059414; WA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 9 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2019	02-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019, the pet owner reported the following event for Broadway Amy, a 14 years old, 9 pound feline of unknown breed. Oct 2005*: The pet began receiving monthly FRONTLINE PLUS CAT (Lot unknown) (package unavailable), applied 1 vial topically between the shoulder blades. 1 Sep 2019: The monthly dose was applied, FRONTLINE PLUS CAT (S40502AX). This dose was more watery then normal. 2 Sep 2019*: The owner noticed flea dirt on the pet. 2 Oct 2019: The monthly dose was applied. 4 Oct 2019: The owner noticed a small amount of fleas on the pet. The owner has not been noticing fleas off of the pet inside the home. The pet is indoor/outdoor but spends minimal time outside. No further medical information expected. Product Quality: On 4 Oct 2019, the owner reported the following issue with an 8 pack of FRONTLINE PLUS CATS (S40502AX). The fourth dose in the 8 pack was more watery then normal and absorbed more quickly. The owner cannot see any obvious differences in the vials. Product return expected. No photos expected. No further information expected. UPDATE 24 OCT 2019: Complaint product has not returned in 14 days. Product return is no longer expected. Two attempts have been made.
04-Oct-2019	UAE; 19US059420; MA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	17-Sep-2019	04-Oct-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Oct 2019, the pet owner reported the following event for a cat with unknown signalment. 17 Sep 2019: The cat received FRONTLINE PLUS CATS (lot unknown, package unavailable). It is unknown if the cat received the product previously. The product's application details are unknown. Fleas were seen prior to product application. 4 Oct 2019: The owner is still noticing fleas. The cat presented to the veterinary clinic. It is unknown if any diagnostics have been performed. Treatments have been initiated with Provecta. The cat's current condition is ongoing. It is unknown how many animals are in the household. Caller did not wish to provide any further details. No further medical information expected.
07-Oct-2019	UAE; 19US059443; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment /	01-Sep-2019*	23-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the owner reported the following event for 3 canines with unknown signalment. Apr 2019*: The dogs started on FRONTLINE PLUS DOG (product unsubstantiated)(lot unknown, Package Unavailable), topically in between the shoulder blades. Sep 2019*: The pets received 1 dose each topically in between the shoulder blades. 23 Sep 2019*: The owner saw a small amount of fleas on the dogs. Sep 2019*: The owner had the home treated by the local exterminator. 24 Sep 2019: The most recent dose was applied. 7 Oct 2019: The owner is still seeing a small amount of fleas.

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ED_005739D_00014391-00277

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						vaccination program not respected)					The dogs are considered an indoor dogs that go outside for occasional walks and potty breaks. There were no fleas seen prior to product use. The pets do receive oatmeal baths on unknown dates as one of the dogs have dry skin. There is 1 other cat in the home that is also on FRONTLINE FOR CATS (lot unknown) that it is unknown if it has fleas. The owner has been treating monthly with FRONTLINE since Apr 2019*. No further information at this time.
07-Oct-2019	UAE; 19US059445; NY; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 11.000 - 13 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Oct-2019	04-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 2019, a pet owner reported the following event for two, 2 to 7 year old, 11 to 13 pound, neutered male Domestic Shorthair cats. 2012: The cats began receiving monthly year round applications of FRONTLINE PLUS CATS (T40109AW) topically between the shoulder blades in one spot. 3 Oct 2019: The cats received the most recent application. 4 Oct 2019*: The owner found 5-6 live, engorged ticks on the cats. The owner physically removed them. The owner has continued to find about 5-7 live, engorged ticks on the cats daily. She physically removes them. The cats are indoor/outdoor and have access to woods. There are no other pets in the home. The cats do not have a history of skin issues. No further information expected.
07-Oct-2019	UAE; 19US059447; NC; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Oct-2019	04-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 7 Oct 2019, the owner reported the following event for 2 felines with unknown signalment. 27 Sep 2019: The owner saw a small amount of fleas on the cats. 4 Oct 2019: One dose of FRONTLINE PLUS CATS (Lot Unknown, Package Unavailable) was applied topically in between the shoulder blades to both cats. The owner's husband stated that the cat that has fleas, licked the product from it's back and seemed more lethargic than usual. 6 Oct 2019: The owner reports still seeing about 5 fleas on one cat. The cats are considered strictly indoor. There were a small amount of fleas seen prior to product use. It is unknown if the pets get baths or if they have a history of skin issues. There are no other pets in the home. This was the owner's first time using FRONTLINE. The cat's current status is unknown. No further information at this time.
07-Oct-2019	UAE; 19US059455; MO; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Unknown **Age:** 6.50 Year(s) **Weight:** 90 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)	04-Sep-2019*	10-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy: On 7 Oct 2019, a pet owner reported the following event for Daisy, a 6.5 year old*, 90 pound*, female, Labrador retriever canine. 4 Sep 2019*: The dog received an application of FRONTLINE PLUS DOG 45-88LBS (S62202AX) in between the shoulder blades. The owner has been applying FRONTLINE PLUS on the dog monthly since Sep 2018*. The owner uses FRONTLINE PLUS year round. 10 Sep 2019*: The pet owner discovered fleas on the dog. 4 Oct 2019*: The dog received another dose of FRONTLINE PLUS. 7 Oct 2019: The pet owner is continuing to see fleas on the dog. The dog lives outside and is walked to a park close to their house where there is a lot of vegetation. The back yard is in a neighborhood, and the owner is unsure how much wildlife is present. The dog frequently visits the woods with the owner. There are no other animals in the home. It is unknown if the dog recieved

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ED_005739D_00014391-00278

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											FRONTLINE PLUS prior to 2018. No further medical information expected.
07-Oct-2019	UAE; 19US059466; MD; U.S.A	**Species:** Canine **Breed:** Shepherd Dog (Others) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 82.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Overdose)	09-Jun-2019*	10-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the pet owner reported the following event for an 82.0 pound, Shepherd Dog, with unknown further signalment. 9 Jun 2019: The pet owner saw fleas. The pet owner applied FRONTLINE PLUS DOG 89-132 LBS (lot unknown) (package unavailable), in an unknown location on the dog. 10 Jun 2019*: The pet owner continues to see fleas on the dog and in the home. Sep 2019*: The pet owner fogged her home 2 weeks in a row on unknown dates in September. There are 3 other cats in the home that have also been treated with FRONTLINE PLUS CATS (See Case 19US059487), to include the new feline. The new feline was introduced into the home on an unknown date in June 2019, and had fleas. All the pets in the home go outside and have access to an open area. No further medical information expected.
07-Oct-2019	UAE; 19US059467; WI; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** - **Age:** 1.00 Year(s) **Weight:** 13 - 15 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019*	02-Oct-2019*	1 Day(s)	D-D	Suspected Adverse Event/ Suspected Lack of Efficacy Claim: On 7 Oct 2019, the owner reported the following event for Mimi a one year old, 15 pound intact female Shih Tzu and Zoey a 2 year old 13 pound intact Shih Tzu. *1 Oct 2019: The dogs have been itching and has had fleas since Aug and the owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS (S61902AL) topically to the skin between the shoulder blades for the first time. *2 Oct 2019: The itching increased and the dogs continued to have fleas. The dogs are exposed to grass daily and there aren't any fleas in the home. No further information available.
07-Oct-2019	UAE; 19US059473; OH; U.S.A	**Species:** Canine **Breed:** Boston Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 20 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Sep-2019	21-Sep-2019*	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, a pet owner reported the following event for a 12 year old, 20 pound, neutered male Boston Terrier. 2007*: The dog began receiving monthly applications of FRONTLINE PLUS DOG 5-22 LBS (T60214AL) topically between the shoulder blades in one spot. The owner treats the dog 6 months out of the year. 3 Aug 2019: The dog received 1 application for the first time this year. No fleas were seen prior. 3 Sep 2019: The dog received another application. No fleas were seen at this time. 21 Sep 2019*: The owner noticed 3-5 live fleas on the dog and has continued to see them daily. There is no flea activity inside the home. The yard is fenced in and there is a deck and 1 tree on the property. The dog goes outside to use the bathroom. It is unknown if the dog receives baths. There is 1 other dog in the home that has fleas, see case 19US059501. No further information expected.
07-Oct-2019	UAE; 19US059479; ME; U.S.A	**Species:** Canine **Breed:** Setter (Irish) **Sex:** F **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	01-Oct-2019	06-Oct-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the pet owner reported the following event for a female Setter (Irish) of unknown signalment. Unknown: The pet began receiving FRONTLINE PLUS DOG 45-88 LBS (Lot unknown) (package unavailable), applied 1 vial topically between the shoulder blades monthly.

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ED_005739D_00014391-00279

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - **Weight:** Unknown				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					1 Oct 2019: The owner applied the most recent dose receiving FRONTLINE PLUS DOG 45-88 LBS (S61313AR). 6 Oct 2019*: Owner found an engorged tick on the pet. It is unknown the species of tick. It is unknown if it was alive or dead at removal. The pet has a large area to run. No further medical information expected.
07-Oct-2019	UAE; 19US059486; MO; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	29-Sep-2019	30-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: 7 Oct 2019 the pet owner reported the following event via mail for a female canine of unknown further signalment. 29 Mar 2019*: Started on FRONTLINE PLUS 23-44 LBS (S61401AK), unknown dose or application site, once monthly. 29 Aug 2019*: The pet owner applied the product. It is unknown if there were fleas on the canine or inside the home at the time of application. 30 Aug 2019*: While at the groomer an unknown number of fleas were noted on the canine. 29 Sep 2019*: The most recent dose was applied. 1 Oct 2019: While at the groomer an unknown number of fleas were noted on the canine. It is unknown where the canine spends the majority of the time, what outside areas she has access to or if she still has fleas. It is also unknown if there are any other pets in the household. No further medical information is expected.
07-Oct-2019	UAE; 19US059487; MD; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	09-Jun-2019*	07-Oct-2019	4 Week(s)	D-D	Suspected Lack of Efficacy: On 7 Oct 2019, the pet owner reported the following event for 3 felines, with unknown signalment. Jun 2019*: The pet owner noticed fleas on the cat on an unknown date. 9 Jun 2019: The pet owner applied 1 dose per feline of FRONTLINE PLUS CATS (lot unknown) (package unavailable), in an unknown location. 10 Jun 2019*: The pet owner continues to see fleas on cats and in the home. Sep 2019*: The pet owner fogged her home 2 weeks in a row on unknown dates in September. There is a dog in the home that has also been treated with FRONTLINE PLUS DOGS 89-132 LBS (See Case 19US059466). One of the 3 cats was introduced into the home on an unknown date in June 2019, and had fleas. All the pets in the home go outside and have access to an open area. No further medical information expected.
07-Oct-2019	UAE; 19US059501; OH; U.S.A	**Species:** Canine **Breed:** French Bulldog **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 16 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Sep-2019	21-Sep-2019*	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, a pet owner reported the following event for a 6 month old, 16 pound, intact female French Bulldog. 3 Sep 2019: The dog received 1 application of FRONTLINE PLUS DOG 5-22 LBS (T60214AL) topically between the shoulder blades in one spot for the first time. No fleas were seen prior to application. 21 Sep 2019*: The owner noticed 3-5 live fleas on the dog and has continued to see them daily. There is no flea activity inside the home. The yard is fenced in and there is a deck and 1 tree on the property. The dog goes outside to use the bathroom. It is unknown if the dog receives baths. There is 1 other dog in the home that has fleas, see case 19US059473. No further information expected.

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ED_005739D_00014391-00280

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
07-Oct-2019	UAE; 19US059517; TX; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	12-Sep-2019*	07-Oct-2019*	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the pet owner called and reported the following for a canine of unknown signalment. 12 Sep 2019*: Pet owner applied FRONTLINE PLUS DOG 5-22 LBS (unsubstantiated) (lot unknown, reporter refused). An unknown volume per animal via an unknown route at an unknown location. 7 Oct 2019*: Pet owner seeing fleas on the canine. It is unknown if the dog presented to a veterinary clinic. It is unknown if any treatments have been administered. The dog's current condition is unknown. It is unknown what environment the canine frequents. It is unknown if the owner bathes the canine. It is unknown if there are any other pets in the household. This is the extent of information known as caller refused to report. No further medical information expected.
07-Oct-2019	UAE; 19US059523; FL; U.S.A	**Species:** Canine **Breed:** Cane Corso **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 130 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Jun-2019	21-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the owner reported the following event for Bella, 6 year old (21 Jul 2012), 130 pound, spayed female, Cane Corso canine. 2014*: The dog began receiving monthly doses of FRONTLINE PLUS DOG 89-132 (lot and expiration unknown, package unavailable). 20 Jun 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (S60111AR) was applied between the shoulder blades. 21 Jun 2019*: The owner started to notice fleas on the dog for the first time. The dog was also itching. 20 Sept 2019: The most recent vial was applied. 7 Oct 2019: The issue is still ongoing. The dog has access to a fenced yard and goes around the neighborhood for walks. There is a cat in the household also being treated and having no issue. No further medical information is expected.
07-Oct-2019	UAE; 19US059530; MI; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** - **Age:** 16.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019*	05-Oct-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the pet owner reported the following event for a 16 year old, female, feline of unknown signalment. 2015*: The pet began receiving FRONTLINE PLUS (Lot unknown), applied 1 vial topically between the shoulder blades monthly. 1 Oct 2019*: The monthly dose was applied. 5 Oct 2019*: The owner found 2 fully engorged, alive ticks. The pet is indoor/outdoor. The environment is heavily wooded. No further medical information expected.
07-Oct-2019	UAE; 19US059545; -; U.S.A	**Species:** Canine **Breed:** Boston Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 17.00 Year(s) **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	01-Jan-2017*	06-Oct-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim:On 7 Oct 2019, the owner reported the following for Mitsy, a female neutered, 17 year old, 15 pound, Boston Terrier. 30 Sep 2019: One vial of the FRONTLINE PLUS DOG 5-22 LBS (R61020AL) was applied topically in between the shoulder blades by the owner. The owner purchased a 3 pack in at an unknown date. 6 Oct 2019: The owner did not notice fleas but large amount of flea dirt after using the product consistently. This is the first time the owner has noticed this on the pets.

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ED_005739D_00014391-00281

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					The dog is indoor mostly but has open acreage for potty breaks and recreation. Fleas are not seen within the home and it is unknown if wildlife is seen within the area. The owner also has cat that is also having issues with flea dirt see case 19US060582.No further medical information is expected.
07-Oct-2019	UAE; 19US059550; TN; U.S.A	**Species:** Canine **Breed:** Setter (English) **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Month(s) **Weight:** 37 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Sep-2019	07-Oct-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the pet owner reported the following event for Kirby, a 7 month old, neutered male, 37 pound, English Setter. 28 Sep 2019: The dog began receiving FRONTLINE PLUS DOG 23-44 LBS (S61009AL). The product was applied directly on the skin between the shoulder blades. No fleas were seen prior to product application. 7 Oct 2019: The owner is still noticing one flea on the dog, and the owner has noticed the pet scratching as well. The dog has access to a small fenced in yard, with no trees or brush on the property. No treatments have been provided at home. The dog's current condition is ongoing. There is one other dog in the household, who is on an unknown oral flea preventative, with no fleas seen. No further medical information expected.
07-Oct-2019	UAE; 19US059551; -; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 16 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Sep-2019*	30-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the owner reported the following event for a 16 pound, female, Shih Tzu (all other signalments unknown). Unknown date: Started on monthly doses of FRONTLINE PLUS DOG 5-22 LBS (S63009BL) given topically, between the shoulder blades, by the owner, on a year round basis. 29 Sep 2019*: Most recent dose of FRONTLINE was applied. 30 Sep 2019*: The owner started seeing a small amount of fleas on the dog. The owner is still seeing fleas on the dog. The owner is not seeing fleas in the home. The dog goes for walks in the neighborhood where there are trees. No further medical information expected.
07-Oct-2019	UAE; 19US059552; GA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 10 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019*	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the owner reported the following event for 2, 10 pounds, felines (all other signalments unknown). Unknown: It is unknown if fleas were seen on cats before application. Unknown date: It is unknown when cats started on the FRONTLINE PLUS. 1 Oct 2019*: The most recent vial of FRONTLINE PLUS CATS (lot unknown, reporter not queried) was applied between the shoulder blades, by the pet owner. 2 Oct 2019*: The cats had fleas. The cats do not get bathed. The owner is not noticing any flea activity in the household. The cats are indoor/outdoor. The owner treated the outside environment with an unknown treatment. There is 1 dog in the household using NEXGARD and is not having any flea issues. No further medical information is expected.
07-Oct-2019	UAE; 19US059568; PA; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** U	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	11-Sep-2019	03-Oct-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the pet owner reported the following event for a 70 pound canine, with remaining signalment unknown. Unknown date: The pet owner applied FRONTLINE PLUS seasonally monthly.

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		Sex qualifier: Unknown **Age:** - **Weight:** 70 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					Aug 9 2019*: The dog received FRONTLINE PLUS DOG 45-88 LBS (S61501AR) monthly. The product was applied directly on the skin between the shoulder blades. 11 Sep 2019: The pet owner applied another dose of FRONTLINE PLUS. 3 Oct 2019: The pet owner noticed fleas, applied another dose of FRONTLINE PLUS. 4 Oct 2019*: The owner is still noticing fleas. The dog has access to a fenced in yard with trees and brush on the property. 5 Oct 2019*: The dog presented to the veterinary clinic. It is unknown if diagnostics had been performed. Treatments have been initiated with oral Capstar and a Seresto collar. The dog's current condition is ongoing. There a total of two canines and two felines in the household. The pet owner reports the cats are not treated with any flea/tick products, and have not noted fleas. The other dog is treated with FRONTLINE PLUS and owner has noticed fleas (See Case 19US059621). No further medical information expected.
07-Oct-2019	UAE; 19US059592; MA; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019	07-Oct-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 07 Oct 2019, the pet owner reported the following event for a male, 8 year, Australian Shepherd, all other signalments unknown. 01 Apr 2019*: The owner applied FRONTLINE PLUS DOG 45-88 LBS (lot unknown/ package unavailable) topically for the first time monthly. 01 Jul 2019*: The owner applied a dose. 15 Jul 2019*: The dog was bathed with unknown shampoo. 01 Sep 2019*: A dose was applied. 16 Sep 2019*: The owner noticed unknown amount of live fleas on the dog and in the house. 01 Oct 2019: A dose was applied. 07 Oct 2019: The owner continues seeing live fleas on the dog and in the home. This is the only pet in the home. The owner is unsure if the product is being applied to the skin or the fur. The owner is unsure if it is being done monthly. The dogs is mostly indoors, but goes for walks in wooded areas. The owner has seen cats outside. No further medical information is expected.
07-Oct-2019	UAE; 19US059597; AZ; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	03-Sep-2019	03-Oct-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 October 2019 2019, the pet owner reported the following event for a 8 month old female German Shepard Dog of unknown signalment. 2 Sep 2019*: Owner noticed the pet was scratching a lot. No live fleas were seen. 3 Sep 2019: The pet began receiving FRONTLINE PLUS DOG 44-88LBS (Lot unknown) (reported not queried) applied 1 vial topically between the shoulder blades for the first time. 4 Sep 2019*: The pet continued to scratching a lot. No live fleas were seen. 15 Sep 2019: The owner applied another dose. 3 Oct 2019: The owner noticed a small amount of fleas on the pet. 4 Oct 2019*: The pet is still scratching. The owner not been noticing fleas off of the pet inside the home . The yard is fenced. The pet has not presented to the veterinarian. No further medical information expected.
07-Oct-2019	UAE; 19US059615; OH; U.S.A	**Species:** Canine **Breed:** West Highland White	1	1	0	**Product used:** FIPRONIL 10%/S	06-Sep-2019*	07-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the pet owner reported the following event for Heidi, a 5 month old (born 7 Apr 2019*), less than 5 pounds, intact female, West Highland Terrier of

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ED_005739D_00014391-00283

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F **Sex qualifier:** - **Age:** 5.00 Month(s) **Weight:** 5 lbs				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					further unknown signalment. 6 Sep 2019*: The reporter noticed Heidi was itching so he applied one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (S61902) topically between her shoulder blades. It's unknown if she's previously received FL+. The reporter assumes no fleas were present at the time of application, though he did not look for any either. Unknown date*: An unknown duration following product application, Heidi was just as itchy as when the FL+ was applied. This lead the reporter to suspect a lack of efficacy with the FL +. 6 Oct 2019: A second vial of FL+ was applied to the puppy in the manner described above because Heidi was still just as itchy as she was prior to receiving FL+ for the first time. Likewise, the pet owner assumes fleas were not present on Heidi, though he did not actively look for any either. Presently, the patient remains just as pruritic as prior to product use. There are no other dogs in the home and the reporter still suspects fleas are not present on Heidi, though he's still not actively checked her for any. No information regarding the dog's external environment is known. No further medical information expected.
07-Oct-2019	UAE; 19US059621; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 23 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Sep-2019	03-Oct-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the pet owner reported the following event for a 23 pound canine, with remaining signalment unknown. Unknown date: The pet owner applied FRONTLINE PLUS seasonally monthly. Aug 9 2019*: The dog received FRONTLINE PLUS DOG 23-44 LBS (S62308AW). The product was applied directly on the skin between the shoulder blades. 11 Sep 2019: The pet owner applied another dose of FRONTLINE PLUS. 3 Oct 2019: The pet owner noticed fleas, applied another dose of FRONTLINE PLUS. 4 Oct 2019*: The owner is still noticing fleas. The dog has access to a fenced in yard with trees and brush on the property. 5 Oct 2019*: The dog presented to the veterinary clinic. It is unknown if diagnostics had been performed. Treatments have been initiated with oral Capstar and a Seresto collar. The dog's current condition is ongoing. There a total of two canines and two felines in the household. The pet owner reports the cats are not treated with any flea/tick products, and have not noted fleas. The other dog is treated with FRONTLINE PLUS and owner has noticed fleas (See Case 19US059568). No further medical information expected.
07-Oct-2019	UAE; 19US059633; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown	07-Oct-2019*	07-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, a pet owner reported the following event for a canine of unknown signalment. Unknown date: The dog has been on FRONTLINE PLUS DOG 5-22 LBS (lot unkonwn, package unavailable) for an unkonwn time. The dog tested anaplasmosis positive and was treated with unknown medications. All further details are unknown as owner was not sure of names of medications. No further medical information expected.

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ED_005739D_00014391-00284

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					
07-Oct-2019	UAE; 19US059637; GA; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 80 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019*	07-Oct-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019 the pet owner called in the following report for Moose, a 11 year old*, 80 pound*, neutered male, Golden Retriever. 1 Jun 2019* - 1 Oct 2019*: The pet owner applied one vial of FRONTLINE PLUS DOG 45-88 LBS (S62408AX) topically between the shoulder blades. 7 Oct 2019: The pet owner notices 3 or 4 fleas* on the pet. The pet has access to a grass yard, where urban wildlife is present. The dog is bathed every 2 to 3 weeks with an unknown pet approved shampoo. There are no other pets in the home. There are no fleas in the home. No further medical information expected.
07-Oct-2019	UAE; 19US059641; CA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2015*	07-Oct-2015*	6 Day(s)	D-A	Suspected Adverse Event: On 7 Oct 2019, the owner reported the following event for a canine of unknown signalment. Unknown: The pet began received FRONTLINE PLUS DOG (lot unknown) (product unsubstantiated). Unknown: The pet passed away on an unknown date. Owner stated the pet passed away a few years ago. No further medical information expected.
07-Oct-2019	UAE; 19US059645; VA; U.S.A	**Species:** Canine **Breed:** French Bulldog **Sex:** F **Sex qualifier:** Neutered **Age:** 14.00 Month(s) **Weight:** 20 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	06-Oct-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the owner reported the following event for CiCi, a 14 month old, 20 pound, spayed female French Bulldog. 1 Oct 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (R62514AL) was applied to the skin between the shoulder blades. 6 Oct 2019: The dog visited a wooded area and owner removed one attached and engorged tick off the dog. The dog has been on FL for the past 7 months without issues. No further information available.
07-Oct-2019	UAE; 19US059666; CA; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 18 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jul-2019	07-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the pet owner reported the following event for Squishy, a 11 year old*, 18 pound, Domestic Medium Hair. 1 Jul 2019: The cat began receiving FRONTLINE PLUS CATS (S40503AX) monthly from an 8 pack. The product was applied directly on the skin between the shoulder blades. It is unknown if fleas were seen prior to product application. 7 Jul 2019*: The pet owner noticed 1-2 fleas on occasion on the pet. The cat has access to an outdoor patio area, with a small open yard. 1 Oct 2019: the most recent date of application. 7 Oct 2019: The owner is still noticing 1-2 fleas on occasion. No treatments have been provided at home. The cat's current condition is ongoing. This is the only pet in the household. No further medical

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											information expected.
07-Oct-2019	UAE; 19US059692; MD; U.S.A	**Species:** Canine **Breed:** Hound Breeds (200 Series) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 60 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	07-Oct-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the owner reported the following event for Chloe, 4 year old, 60 pound, spayed female, Hound breed canine. 1 Oct 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) was applied between the shoulder blades. 7 Oct 2019: The owner noticed fleas for the very first time. The dog was also itching. The dog has access to an open area. The dog went to visit another pets home that was also battling fleas. The dog has received the product since 2014* with no issue. There is a cat in the household also being treated with FRONTLINE and experiencing no issue. No further medical information is expected.
07-Oct-2019	UAE; 19US059697; OH; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Aug-2019*	01-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the owner reported the following event for 3 cats (signalment unknown). Apr 2019*: The cats started on monthly applications of FRONTLINE PLUS CATS (lot unknown, packaging unavailable) topically between the shoulder blades. 1 Sep 2019: The cats had fleas and one vial of FRONTLINE PLUS CATS was applied to each cat. 1 Oct 2019: The cats continued to pick up fleas and were given another application of Frontline Plus. The owner is picking off around 6 fleas off each cat. The cats are indoor/outdoor and goes outside for an hour each day (environment unknown). There are no other pets in the home. No further information available.
07-Oct-2019	UAE; 19US059733; CA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Week(s) **Weight:** 2.5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Unknown Vaccines; Unknown Antibiotics; Unknown Dewormer; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Oct-2019	07-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 7 Oct 2019, the owner reported the following event for Stella, 8 week old, 2.5 pound, spayed female, Domestic Shorthair feline. 7 Oct 2019: One vial of FRONTLINE PLUS CATS (M41702AW) was applied between the shoulder blades for the very first time. After a few minutes the cat began experiencing hyperactivity and began rolling around like the product was burning. The pet did not present to the clinic and no treatment was provided. The cat began settling down and the time of the call. The cat received unknown vaccines, antibiotics, and deworming on unknown dates within the last 30 days. No further medical information is expected.
07-Oct-2019	UAE; 19US059734; NJ; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 14 lbs	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical /	03-Oct-2019	07-Oct-2019	4 Day(s)	D-A	Suspected Adverse Event: On 7 Oct 2019, the pet owner reported the following event for Logan, a 6 year old, 14 pound, female Domestic Shorthair (further signalment is unknown). Unknown date: The pet received FRONTLINE PLUS CATS (lot unknown) (package unavailable) topically between the shoulder blades monthly. 3 Oct 2019: Owner applied the monthly dose. Purchased from a retail outlet. 7 Oct 2019: The pet began experiencing a seizure. The pet began

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ED_005739D_00014391-00286

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** Yes					rolling around, shaking, had an elevated heart rate, and then passed away. The pet did not present to the veterinary clinic. No treatment was initiated. A necropsy was not performed. The pet was healthy on date of administration. The pet previously received FRONTLINE PLUS CATS for and unknown amount of years with no adverse effects noted. The pet has no pertinent medical history. The pet has no history of drug reactions. No further medical information expected
07-Oct-2019	UAE; 19US059763; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	09-Sep-2019	10-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 7 Oct 2019, the pet owner reported the following event, for a 2 year old, feline of further unknown signalment. 9 Sep 2019: The pet owner applied 1 dose of FRONTLINE PLUS CATS (S40606AW), between the shoulder blades, in one spot, for the first time on the cat. 10 Sep 2019*: The cat was scratching its head area and the pet owner noticed fleas on the cat. It is unknown if the pet owner noticed fleas prior to application of FRONTLINE PLUS CATS. Unknown date and 6 Oct 2019: The pet owner bathed the cat in Dawn dish soap. She is still seeing fleas on the cat. The cat is flicking its ear and has missing hair in various spots which began on an unknown date. The cat is primarily inside the home, but has access to a deck and has escaped outside twice in the last 6 months. The pet owner is not seeing any fleas in the home. Currently she sees 3 fleas on the cat. There are no other pets in the home. No further medical information expected.
08-Oct-2019	UAE; 19US059786; NC; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Mixed **Age:** - **Weight:** 48 - 80 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	24-Aug-2019	Sep-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Oct 2019, the pet owner reported the following event for Bear, 80 pound canine of unknown signalment and Zoe a 48 pound canine of unknown signalment. 2017*: The pets began receiving FRONTLINE PLUS 45-88 LBS (Lot unknown) (package unavailable), applied 1 vial per animal topically between the shoulder blades monthly, year round. Aug 2019*: Owner noticed the pet scratching more than usual. 24 Aug 2019: The monthly dose was applied FRONTLINE PLUS 45-88 LBS (S62503AX). No live fleas were seen at this time. Sep 2019*: Zoe presented to the veterinary clinic for scratching and hair loss. Veterinarian noticed a moderate amount of fleas. Treatment was initiated with a steroid injections. 24 Sep 2019: The monthly dose was applied. 1 Oct 2019*: The owner still noticing a moderate amount of fleas on the both pets. The owner has not been noticing fleas off of the pet inside the home. There a total of 2 canines and 2 felines in the household. The yard is wooded. Both felines are treated with Frontline Plus Cats. There are no fleas on the cats at this time. No further medical information expected.
08-Oct-2019	UAE; 19US059802; NY; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 44 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	23-Sep-2019	06-Oct-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Oct 2019, the pet owner reported the following event for a canine of unknown signalment 2018*: The pet began receiving FRONTLINE PLUS 23-44 LBS (Lot unknown)(package unavailable), applied 1 vial topically between the shoulder blades monthly. 23 Sep 2019: The monthly dose was applied. 6 Oct 2019: The owner found an attached, dead tick. 7 Oct 2019: The owner found a fully engorged, dead tick. The pet spends regular time in the woods. The tick species in

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ED_005739D_00014391-00287

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** Yes					unknown. No further medical information expected.
08-Oct-2019	UAE; 19US059821; NJ; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown flea dip; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Sep-2019	07-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Oct 2019, the pet owner reported the following event for 3 Shih Tzu canines, of further unknown signalment. Sep 2019*: The pet owner applied 1 dose of FRONTLINE PLUS DOG 5-22 LBS (SRA00286192AL, invalid lot number), between the shoulder blades in one spot to the 3 dogs. 5 Oct 2019*: The pet owner treated the 3 dogs with an unknown flea dip. 6 Oct 2019: The most recent date of application to all 3 dogs. 7 Oct 2019*: The pet owner is seeing 1 to 2 fleas on each dog. The dogs are in good health and do not have any skin issues. They have access to a fenced in yard that is bare, with no grass. The pet owner has not seen any flea activity in the home, but her husband has noted that he does see fleas inside the home. No further medical information expected.
08-Oct-2019	UAE; 19US059845; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	07-Oct-2019	08-Oct-2019	1 Day(s)	D-D	Suspected Adverse Event: On 8 Oct 2019, the owner reported the following event for a canine with unknown signalment. 7 Oct 2019: One dose of FRONTLINE PLUS (product unsubstantiated)(lot unknown, reporter not queried) was applied via unknown route and location. 8 Oct 2019: The owner stated that is it seemed like the pet was itching and scratching more than usual. This was pet's first time using FRONTLINE. It is unknown if fleas were seen prior to product use. It is unknown if any other dogs were in the home. It is unknown if the pet has any skin issues or baths on a normal basis. The pet's environment and lifestyle is unknown. No further information at this time.
08-Oct-2019	UAE; 19US059867; MI; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 17 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	01-Jun-2019	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Oct 2019 the pet owner reported the following event for two small crossbred canines, 3 to 10 years old*, 17 pounds*, and male neutered. 1 Jun 2019* - 1 Sep 2019*: The owner applies one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package ripped) topically between the shoulder blades to each pet. 1 Oct 2019*: the pet owner applied FRONTLINE PLUS to each pet. 2 Oct 2019*: The owner noticed a small amount of fleas on each pet. The owner bathed the pets in an unknown pet shampoo. 3 Oct 2019*: The owner bathed the pets in an unknown pet shampoo. 4 Oct 2019*: The owner bathed the pets in an unknown pet shampoo. 8 Oct 2019: The pet owner continues to see a few fleas on each pet. The pet owner applied one vial of FRONTLINE PLUS to each pet. The pets have access to a grass yard, where urban wildlife is present. The pet owner stated, he traps wildlife and the pets have access where the wildlife is trapped. There are no other pets in the home. There are no fleas seen in the home. The pets were in good health prior to application. The owner has been using Frontline plus seasonally for an unknown amount of time. No further medical information expected.

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ED_005739D_00014391-00288

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
08-Oct-2019	UAE; 19US059870; MI; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	15-Apr-2019*	01-Jun-2019	N/A	D-D	Suspected Adverse Event and Suspected Lack of Efficacy Claim : On 8 Oct 2019, the pet owner reported the following event for 2 dogs with unknown signalment. 15 Apr 2019*: The dogs began receiving FRONTLINE PLUS DOGS 89-132 LBS (R62114AR) for the first time this year on a monthly seasonal basis from Apr- Sep. There were 6 vials purchased on an unknown date from PetMeds. The product was applied directly on the skin between the shoulder blades. Fleas were not seen prior to product application. 15 May 2019- 15 Jun 2019: The monthly dose was applied. Jun 2019*: The dogs began scratching and continued to scratch all summer, but the pet owner did not check for fleas. 15 Jul 2019 - 15 Aug 2019: The monthly dose was applied. 21 Aug 2019*: The dogs were bathed in an unknown dog shampoo to help alleviate the itching. 12 Sep 2019: The monthly dose was applied. 6 Oct 2019: The owner began noticing an unknown amount of fleas. The dogs have access to a fenced yard and they go on daily leash walks. It is unknown if the dogs have presented to the veterinary clinic. No treatments have been provided at home. The dogs' current condition is ongoing. There a total of 2 canines and no other animals in the household. The client is concerned they have a bad batch of product. No further medical information expected.
08-Oct-2019	UAE; 19US059895; MO; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** X **Sex qualifier:** Mixed **Age:** - **Weight:** Unknown	6	6	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019*	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Oct 2019, the pet owner reported the following event for 6 felines of unknown signalment. 2015*: The pets began receiving FRONTLINE PLUS CATS (Lot unknown) (package unavailable), applied 1 vial per animal topically between the shoulder blades monthly. 1 Oct 2019*: Owner applied the most recent dose, FRONTLINE PLUS CATS (S41404AW). 2 Oct 2019*: The owner noticed a small amount of fleas on the pet. The owner not been noticing fleas off of the pet inside the home . The owner recently moved into a new house. There recently was a foster kitten in the home that did have some fleas. The cats are indoor only. No further medical information expected.
08-Oct-2019	UAE; 19US059898; VA; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 43 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Doxycycline; enrofloxacin; unknown anesthesia; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Route not indicated /	07-Oct-2019	07-Oct-2019	0 Day(s)	D-B	Suspected Adverse Event: On 8 Oct 2019, the owner reported the following event for Jezebelle, an 11 year old, 43 pound, spayed female Golden Retriever. 26 September 2019: Dog has surgery due to massive infection and was given Doxycycline and enrofloxacin as treatment. 7 Oct 2019: The dog was recovering and doing well so the owner applied one vial of FRONTLINE PLUS DOG 45-88 LBS (S62202AX) topically to the skin between the shoulder blades and a few drops to the tail and hind legs. Within 30 minutes the dog was moaning, experiencing paralysis, and her temperature went up (values unknown). 8 Oct 2019: The dog presented to the clinic, it is unknown if treatments are being given. The dog is treated with FL monthly year round and has been for years without issues. There is one other treated dog in the home who isn't have any issues. No further information available.

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ED_005739D_00014391-00289

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						recommended)					
08-Oct-2019	UAE; 19US059900; IL; U.S.A	**Species:** Feline **Breed:** Feline various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** 3 - 10 lbs*	6	6	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Sep-2019	08-Oct-2019	4 Week(s)	D-D	Suspected Lack of Efficacy and Adverse Event Claim: On 8 Oct 2019, the pet owner reported the following event for 6 cats, weighing 3-10 pounds*, with remaining signalment unknown. 10 Sep 2019: The cats began receiving FRONTLINE PLUS CATS (S41003AW). The product was applied directly on the skin between the shoulder blades for the first time. Fleas were not seen prior to product application, but the cats were scratching as if they had fleas. 8 Oct 2019: The owner is still noticing fleas. The cats are indoor only. No treatments have been provided at home. The cats' current conditions are ongoing. There a total 17 cats, 6 that live indoor only, and 11 that are outdoor only. The owner did not treat the outdoor cats, it is unknown if fleas have been seen on them. No further medical information expected. UPDATE 14 Oct 2019: The owner reported the 6 indoor cats vomited after FRONTLINE PLUS use at an unknown timeframe. The cats do groom each other.
08-Oct-2019	UAE; 19US059905; IA; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Feb-2019	08-Oct-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Oct 2019, the pet owner reported the following event for Blue, 15 pounds, 4 year* (1 Feb 2015*), neutered male, Domestic Mediumhair. 27 Feb 2019: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (S41404AW) to the skin between the shoulder blades monthly for the first time of the year. 27 Mar 2019: A dose was applied. 15 Apr 2019*: The owner noticed an unknown quantity of live fleas on the pet and in the home. 27 Apr 2019: The owner continued monthly application. 27 Sep 2019: A dose was applied. 08 Oct 2019: An unknown quantity of fleas are still being seen on the cat and in the home. The cat is indoor only. This is the only pet in the home, although the owner mentioned cat sitting after fleas were already present. There are no previous skin or flea issues. The owner occasionally bathes with an unknown feline flea shampoo on unknown dates. No further medical information is expected.
08-Oct-2019	UAE; 19US059914; OH; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown pet shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Oct-2019	05-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Oct 2019, the pet owner reported the following event for two canines, of unknown signalment. 4 Oct 2019: The pet owner noticed that the two dogs were itching and bathed both dogs in a unknown pet shampoo. The pet owner then saw fleas on both of the dogs. Approximately 30 minutes later, the pet owner applied 1 dose of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable), in one spot, between the shoulder blades to each dog. It is unknown if the pets were naturally dry prior to application. 5 Oct 2019*: The pet owner is still seeing approximately 2 fleas on each dog. The pet owner does not see fleas in the home. The dogs go outside just for potty breaks in a yard with an invisible fence that has grass and some bushes. The pet owner has used FRONTLINE PLUS previously at unknown intervals for an unknown length of time. No further medical information expected.
07-Oct-2019	UAE;	**Species:** Canine	2	2	0	**Product used:**	19-Sep-2019	06-Oct-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 6 Oct 2019, the pet owner

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ED_005739D_00014391-00290

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19US059915; MA; U.S.A	**Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					reported to a social media outlet the following event for an unknown amount of dogs with unknown signalment. This report was discovered on 7 Oct 2019. 19 Sep 2019: The dogs received FRONTLINE PLUS DOG 23-44 LBS (lot unknown, not given). It is unknown if the dogs have previously received the product. The pet owner purchased a 6 pack on 17 Sep 2019 from a retail store. Product application details are unknown. It is unknown if fleas were seen prior to product application. 6 Oct 2019: The owner is noticing an unknown amount of fleas. The dogs' excursion details are unknown. It is unknown if the dogs have presented to the veterinary clinic. It is unknown if treatments have been provided at home. The dogs' current condition is ongoing. It is unknown how many animals are in the household. No further medical information expected. UPDATE 30 Oct 2019: Contact information was updated. No further medical information expected.
08-Oct-2019	UAE; 19US059921; -; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 36 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	24-Sep-2019	05-Oct-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Oct 2019, the owner reported the following event for Shyan, 10 year old (5 Aug 2009), 36 pound, spayed female medium crossbreed canine. 8 Sept 2019: The owner purchased 6 doses of FRONTLINE PLUS DOG 23-44 LBS (lot unknown, package unavailable). 24 Sept 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown, package unavailable) was applied between the shoulder blades. 5 Oct 2019: The dog went out hunting in a heavily wooded area and came back with 25 ticks. The majority of the ticks were attached and all of them were alive. The owner removed the ticks. The dog has used the product year round since 2017* with no issue. There are no other pets in the home. No further medical information is expected.
08-Oct-2019	UAE; 19US059941; -; U.S.A	**Species:** Feline **Breed:** Feline (DO NOT USE) **Sex:** U **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	25-Sep-2019	08-Oct-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Oct 2019, the owner reported the following even for two felines, 14-16 years* of age with remaining signalment unknown Sep 2019*: The owner noticed the cats were scratching more than usual. A bath was given using unknown shampoo. 25 Sep 2019: The owner applied the first dose of FRONTLINE PLUS CATS (lot unknown, reporter not queried) to both cats via unknown route and location. 8 Oct 2019: The owner noticed 6-8 fleas on each cat. The cats are considered strictly indoor. There were no fleas seen prior to product use. It is unknown if the cats have a history of skin issues. There are no other pets in the home. This was the owner 's first time using FRONTLINE on the cats. No further information at this time.
08-Oct-2019	UAE; 19US060032; -; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 19 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	01-Oct-2019*	08-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Oct 2019, the pet owner reported the following event for Kacie, 19 pounds, 7 year, spayed female, Shih Tzu mix. 01 Jan 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 5-22 LBS (S61006AL) to the skin between the shoulder blades monthly for the first time year round. 01 Sep 2019*: A dose was applied. 05 Sep 2019*: The owner noticed 2 live fleas on the pet. 01 Oct 2019*: A dose was applied. 07 Oct 2019: The pet was bathed with an unknown oatmeal

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ED_005739D_00014391-00291

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					shampoo. 08 Oct 2019: The owner reports still seeing about 2 live fleas on the pet. This is the only pet in the home. The pet receives baths with unknown oatmeal shampoo as needed for allergies. There is a history of environmental allergies. The owner reports the possibility of urban wildlife and outdoor cats since she lives in a rural area. The pet was taken to a veterinarian on an unknown date and received an unknown steroid injection and Apoquel. The owner reports the pet is losing fur from allergies and the fleas. No further medical information expected.
08-Oct-2019	UAE; 19US060052; AR; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Apr-2019*	18-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 8 Oct 2019, the pet owner reported the following event for a year old dog with otherwise unknown signalment. 2015*: The dog began receiving FRONTLINE PLUS DOG 89-132 LBS (lot unknown, package unavailable) monthly on s seasonal basis from Apr to Oct each year. There is an unknown purchase history. The product was applied directly on the skin between the shoulder blades. Fleas were not seen prior to product application. 1 Aug 2019* – 1 Sep 2019*: The monthly dates of application. 18 Sep 2019*: Fleas were first noticed, so the pet owner applied an additional dose of product. 2 Oct 2019: The most recent date of application. 6 Oct 2019*: The dog was bathed with Dawn dish detergent. 8 Oct 2019: The owner is still noticing moderate fleas. The dog has access to an open area outside that other neighborhood dogs also have access to. The dog has not presented to the veterinary clinic. No treatments have been provided at home. The dog's current condition is ongoing. There a total of 2 canines and no other animals in the household. The other dog in the home is elderly; it stays indoors and is not on flea prevention. No further medical information expected.
08-Oct-2019	UAE; 19US060063; KS; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 7 - 11 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Unknown Dewormer; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jan-2019*	29-Aug-2019*	24 Day(s)	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 8 Oct 2019 the pet owner reported the following event for Princess, a 18 year old*, 7 pound*, spayed female, unknown feline. 5 Jan 2019* - 5 Jul 2019*: The pet owner applies one vial of FRONTLINE PLUS CATS (R41105AW) topically between the shoulder blades once monthly and year round to Princess. 1 Aug 2019*: The pet owner adopted 2 felines from Korea. 5 Aug 2019: The pet owner applied FRONTLINE PLUS to Princess only. 29 Aug 2019*: The pet owner noticed fleas on Princess only. Unknown Date: Princess started to vomit. The owner feels that Princess contracted an unknown parasite from the fleas. The pet owner treated Princess with an unknown dewormer at an unknown dose for an unknown amount of time. The pet was not seen by a veterinarian for this issue. 6 Sep 2019: The pet owner applied FRONTLINE PLUS to Princess only. 8 Sept 2019: The pet owner applied FRONTLINE PLUS to Ollie (another feline). 7 Oct 2019: The pet owner continues to see an unknown amount of fleas on Princess only. The pets have access outside, where urban wildlife and neighborhood pets are present. The third feline which is one of the two from Korea has not received any flea and tick preventative.

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ED_005739D_00014391-00292

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											When asked reporter stated she does not look for fleas on the two felines from Korea. The pets were in good health prior to the application. The pets are not bathed. No further medical information expected.
08-Oct-2019	UAE; 19US060081; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Oct-2019	08-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Oct 2019, the pet owner reported the following event for 3 cats of mixed sexes, all other signalments unknown. 07 Apr 2019: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (S41305AW) to the skin between the shoulder blades of each cat monthly for the first time of the season. 07 Oct 2019: A dose was applied. 08 Oct 2019: The owner noticed an unknown amount of fleas and flea dirt on the cats at the veterinary clinic. There is also 1 dog in the home on NEXGARD with no fleas seen that goes outside frequently. The cats are indoors only. No baths have been given. The owner has not seen any fleas within the home. The home is in the country and wildlife has been seen. No further medical information expected.
08-Oct-2019	UAE; 19US060084; OH; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Jun-2019	01-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim:On 8 Oct 2019, the owner reported the following event for a male, feline(all other signalments unknown). 30 June 2019: The cat started on FRONTLINE PLUS on a monthly basis. 30 Sept 2019: The most recent vial of FRONTLINE PLUS CATS (A41103AW) was applied between the shoulder blades,by the pet owner. 1 Oct 2019*: The cat was scratching to the point that fur was falling out, but no fleas were seen on cat. The owner says that cat has FAD. 7 Oct 2019: The cat present to clinic and no treatment was provided. The owner did not bathed cat. The owner is not noticing any flea activity inside the household. The cat has access to a garage. There are 2 other cats in the household using FRONTLINE PLUS but are not having any issues with fleas. No further medical information is expected.
09-Oct-2019	UAE; 19US060088; -; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 10.000 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Oct-2019	08-Oct-2019*	1 Day(s)	D-B	Suspected Adverse Event: On 9 Oct 2019, the owner reported the following event for Lilly, a 10-12 pound*, 4 year old*, spayed female Shih Tzu. 7 Oct 2019: The owner applied FRONTLINE PLUS DOG 5-22 LBS (Lot Unknown, Package Unavailable) topically in between the shoulder blades. 8 Oct 2019 - 9 Oct 2019: The owner noticed that Lilly was constantly sniffing and gasping for air as if she was having a panic attack. Her current symptoms are intermittent. Treatment has not been given. Pet does not have any known allergies. This was her first time receiving FRONTLINE. No further information at this time.
09-Oct-2019	UAE; 19US060104; NY; U.S.A	**Species:** Feline **Breed:** Feline various breeds **Sex:** X **Sex qualifier:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products**	01-Oct-2019	08-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim:On 9 Oct 2019, the owner reported the following event for 2 Felines , weighing 8-10 pounds* and between 5-7 years of age, all other signalment unknown. 1 Sep 2019: One vial of the FRONTLINE PLUS CATS (S41006AW) was applied topically in between the shoulder blades by the owner. The owner purchased a 6 pack at an unknown date.

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ED_005739D_00014391-00293

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 5.00 Year(s) **Weight:** 8 - 10 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					1 Oct 2019: One vial of the FRONTLINE PLUS CATS (S41006AW) was applied topically in between the shoulder blades by the owner. 8 Oct 2019: The owner noticed 5 ticks engorged and feeding on the cats. The cats are indoor/outdoor. The owner has not noticed wildlife in the area. There is one other cat in the home that is not having any issues with ticks. This is the second dose of FRONTLINE PLUS for the cats and it is unknown if ticks were seen prior to the use of the product.It is unknown if ticks are still attached. No further medical information is expected.
09-Oct-2019	UAE; 19US060111; CT; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	15-Sep-2019*	01-Oct-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019 the pet owner reported the following event via mail for a male canine of unknown further signalment. Unknown date: Started on FRONTLINE PLUS DOG 5-22 LBS (lot number unknown, package unavailable) (product unsubstantiated), unknown volume, route, application site, or frequency. Sep 2019: The pet owner applied the product on two unknown dates. It is unknown if she was seeing fleas at the time of either application. 1 Oct 2019: The pet owner removed 3 adult fleas on the canine and approximately 6 larvae. It is unknown where the canine spends the majority of the time or what outside areas he has access to. It is also unknown if there are any other pets inside the home. No further medical information is expected.
09-Oct-2019	UAE; 19US060119; IL; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 11.5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	05-Sep-2019	12-Sep-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 09 Oct 2019, the pet owner reported the following event for Kit Kat, 11.5 pounds, 9 year, spayed female, Domestic Mediumhair. 05 Jan 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (S401177AW) to the skin between the shoulder blades monthly for the first time. 05 Sep 2019: The owner applied a dose. 12 Sep 2019: The cat went outside briefly and came back inside with 2 live fleas. 24 Sep 2019*: The owner noticed an increased amount of fleas on the pet and flea dust on the covers where the cat sleeps. 26 Sep 2019: Per veterinarian recommendations, the owner applied another dose. 09 Oct 2019: The owner is continuing to see 1 to 2 live fleas on the cat. This is the only pet in the home. The cat is indoors only. The owner has not seen live fleas in the home, but did get it professionally treated. The owner reports the cat had fleas last year while not on any preventative and has flea allergies. The owner reports there are oppossums and outside cats in the neighborhood. It is unknown if a bath has been given. The cat was prescribed a Capstar tablet. No further medical information expected.
09-Oct-2019	UAE; 19US060133; CA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 7 - 10 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products	04-Sep-2019*	25-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019, the owner reported the following event for 2 cats weighing 7 and 10 pounds (signalment unknown). 4 Sep 2019: The cat had fleas for an unknown length of time and one vial of FRONTLINE PLUS CATS (S40502AX) was applied topically to the skin between the shoulder blades. 25 Sept 2019: The cats continued to pick up fleas and another application was given.

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ED_005739D_00014391-00294

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					The owner is finding a small number of fleas and the cats are indoors. The owner is not seeing fleas in the home. The cats are treated on a as needed basis and there aren't any other pets in the home. No further information available.
09-Oct-2019	UAE; 19US060137; AR; U.S.A	**Species:** Canine **Breed:** Spaniel (Cocker) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 24 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Jul-2019*	09-Oct-2019	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019 the pet owner reported the following even for Blondie, a 4 year old*, 24 pound*, spayed female, Cocker Spaniel. 1 Jul 2019*: The pet owner noticed a large amount of fleas on the pet. 15 Jul 2019*: The pet owner applied one vial of FRONTLINE PLUS DOG 23-44 LBS (S61009AL) topically between the shoulder blades for the first time. 15 Aug 2019* - 15 Sep 2019*: The pet owner applied FRONTLINE PLUS monthly. 9 Oct 2019: The pet owner continues to notice 1 to 2* fleas on the pet. The pet lives in a room attached to the home and has access outside to a fenced in yard. It is unknown there is wildlife present in the yard. There are no other pets in the home. There are no fleas seen in the home. The pet is not bathed while on FRONTLINE PLUS. No further medical information expected.
09-Oct-2019	UAE; 19US060140; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	05-Oct-2019	06-Oct-2019	1 Day(s)	D-D	Suspected Adverse Event: On the 9 Oct 2019, a pet owner reported the following event for a feline of unknown signalment. 5 Oct 2019: The pet owner applied for the first time 1 dose of FRONTLINE PLUS CATS (S40606AW), topically between the shoulder blades. 6 Oct 2019: The cat began to experience emesis off and on throughout the day since the early morning. 9 Oct 2019: In addition to the emesis the cat is now also experiencing diarrhea. The issue is ongoing. It is unknown if the cat has seen her veterinarian for these symptoms and if she has received any treatment since the pet owner declined to give additional details for the case.
09-Oct-2019	UAE; 19US060150; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	09-Oct-2019*	09-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019, a pet owner reported the following for a feline of unknown signalment. Unknown Date: The owner applied FRONTLINE PLUS CATS (lot unknown, package unavailable) it is unknown if the cat had fleas, and unknown amount of time after the cat still had fleas. All other information is unknown as owner disconnected during report. No further medical information expected.
09-Oct-2019	UAE; 19US060154;	**Species:** Canine **Breed:** Canine	1	1	0	**Product used:** FIPRONIL	14-Sep-2019	15-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019, the pet owner reported the following event for a 13 year old, 68.0 pound, male

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ED_005739D_00014391-00295

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	TN; U.S.A	(unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 68.0 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					canine, of further unknown signalment. 14 Sep 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, reporter not queried), in one spot, between the shoulder blades to the dog. 15 Sep 2019*: The pet owner began seeing fleas on the dog. 28 Sep 2019: The pet owner bathed the dog with an unknown pet flea shampoo. 1 Oct 2019: The pet owner applied 1 dose of FRONTLINE PLUS DOG 45-88 LBS to the dog. 2 Oct 2019: The pet owner bathed the dog in Dawn dish soap. The pet owner is currently seeing 1 to 5 fleas. She has not noticed any fleas in the home, and she is vacuuming 3 times a day. The dog has access to an open yard and but typically takes potty breaks on the gravel. The yard has grass, tomato plants and is not fenced in. The dog is in good health. The pet owner has used FRONTLINE PLUS DOG 45-88 LBS monthly year round since and unknown date. No further medical information at this time.
09-Oct-2019	UAE; 19US060159; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 85 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Human baby shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	08-Jul-2019	09-Oct-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019 a pet owner reported the following event for Porkchop, an 85 pound, male dog of unknown other signalment. Unknown date: Owner started seeing fleas on the dog. 8 Jul 2019* Owner applied FRONTLINE PLUS DOG 89-132 LBS (S62006BX) to the skin between the animal's shoulder blades for the first time of the season, then again Aug 2019*, and Sep 2019* 9 Jul 2019*: Dog still has live fleas on him. 6 Oct 2019: Owner gave dog a bath with human baby shampoo. 7 Oct 2019: Owner applied FRONTLINE PLUS. 9 Oct 2019: Dog has fleas dirt and 5 to 10 live fleas on him. The dog lives inside, also going outside in a fenced grass yard with a wooded area behind the fence, and sometimes the dog goes back there where wildlife is seen. There are two other dogs in the home who live inside, going outside, and using an unknown flea collar. Owner is getting bitten by fleas in the home. It is unknown if the owner has treated the home or the yard. The owner has used the product seasonally for an unknown number of years and has not had a flea problem previously. No further medical information expected.
09-Oct-2019	UAE; 19US060162; -; U.S.A	**Species:** Canine **Breed:** Chowchow **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 24 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	30-Jul-2019*	09-Oct-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019, the owner reported the following event for Skippy, 14 year old (1 Jun 2005), 24 pounds, neutered male, Chowchow canine. 30 Jul 2019*: The owner purchased a 3 pack of FRONTLINE PLUS DOG 23-44 LBS (S61009AL) and the dog began receiving monthly doses for the first time this year. 15 Aug 2019*: The owner started to notice fleas for the first time. Another vial was applied. The flea issue persisted. 30 Sept 2019: The third vial was applied. No fleas were noted in the home. 9 Oct 2019: The fleas issue is still ongoing. The dog has access to a beach. The dog has received the product on prior unknown dates. There are no other pets in the household. No further medical information is expected.
09-Oct-2019	UAE; 19US060168;	**Species:** Canine **Breed:** Terrier	1	1	0	**Product used:** FIPRONIL	20-Feb-2019*	09-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019, the pet owner reported the following event for Sadie, a 7 year old, 12 pound*,

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ED_005739D_00014391-00296

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	WA; U.S.A	Breeds (500 Series) **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 12 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown flea shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					spayed female, Terrier mix. Oct 2017*: The canine has received one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (S60714) applied topically between the shoulder blades monthly around the twentieth and the most recent dates of application are as follows: 20 Feb 2019*, 20 Mar 2019*, 20 Apr 2019*, 20 May 2019*, 20 Jun 2019*, 20 Jul 2019*, 20 Aug 2019*, and 10 Sep 2019. It's unknown if she's previously received FL+. The earliest month in which a small volume of fleas were seen on Sadie at the time of FL+ application can't be confirmed because the reporter does not recall. Unknown dates: It cannot be confirmed how long after the earliest corresponding FL+ application before the reporter continued to find a small amount of fleas on the canine and the primary reason the reporter even looked for fleas was because Sadie was chewing at her feet, causing the local hair coat to fall out and the skin to become red. Likewise, she's continued to see a small volume of fleas on Sadie at the time of every subsequent FL+ application. Although fleas were not seen in the home, on an unknown date in Sep, the reporter proactively bombed the home using an unknown product. Around the same time, she also bathed Sadie with an unknown flea shampoo to remove the small number of fleas on her. Presently, the reporter continues to find a small volume of fleas on the canine. Likewise, she's not finding fleas anywhere in the home. There are no other resident animals though there have been visiting animals. Details regarding dates and conditions of the animals that visited the home are unknown. Sadie goes on an hour leash walk in the morning and a 20 minute leash walk in the afternoons, and is typically limited to walking on the sidewalk. There is grass around including in the front yard, but the pet owner dissuades Sadie from going onto the front lawn. There are no
09-Oct-2019	UAE; 19US060173; MO; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 100 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Jun-2019*	06-Oct-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019, the owner reported the following event for a 100 pound canine (all other signalments unknown). June 2019: The dog started on FRONTLINE PLUS on a monthly basis. 25 Sept 2019: The most recent vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown, package unavailable) was applied between the shoulder blades, by the pet owner. 6 Oct 2019: The dog went to the groomer and fleas were seen on the dog. 9 Oct 2019: The amount of fleas increase after grooming visit. The owner is not noticing any flea activity in the household. The owner treated the outside environment with an unknown treatment. No further medical information is expected.
09-Oct-2019	UAE; 19US060175; KY; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 7 - 12 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	16-Apr-2019	25-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019 the pet owner reported the following event for two Maltese canines weighing 7 to 12 pounds of unknown further signalment. 16 Apr 2019: The two canines started on FRONTLINE PLUS DOG 5-22 LBS (lot number unknown, package unavailable), 1 vial topically, in between the shoulder blades once monthly. There were no fleas seen at the time of application. 16 May 2019: The pet owner applied one dose to each canine. 25 May 2019*: The pet owner began seeing an unknown number of fleas on both canines. 16 Sep 2019: The most recent dose was applied to both canines. Currently, the pet owner is seeing a large amount of fleas on both

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ED_005739D_00014391-00297

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					canines and inside the home. The two canines spend the entirety of their time inside the home. There are no other pets in the household. No further medical information is expected.
09-Oct-2019	UAE; 19US060177; TX; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019*	09-Oct-2019*	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 09 Oct 2019, an owner reported the following event in an unknown dog of unknown signalment. 01 Oct 2019*: The owner administered one FRONTLINE PLUS DOGS (product size unsubstantiated)(lot unknown, package unavailable) topically in-between the shoulders for the first time. It is unknown if fleas were seen at the time of application. 09 Oct 2019*: An unknown amount of fleas were seen on the base of the tail. The dog is indoor-outdoor in an unknown environment. It is unknown if other animals are in the home. The status of the dog is unknown. Dates approximate for reporting purposes. Owner was inquiring on where to apply the product only. No further medical information expected.
09-Oct-2019	UAE; 19US060179; -; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 62 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	05-Aug-2019*	15-Aug-2019*	10 Day(s)	D-C	Suspected Adverse Event and Lack of Efficacy: On 09 Oct 2019, the pet owner reported the following event for Gertrude, 62 pound, 4 year*, spayed female, Labrador Retriever mix. 05 Aug 2019*: The pet owner applied the contents of 1 vial FRONTLINE PLUS DOG 45-88 LBS (P61401AR) topically for the first time since 2016* monthly. 15 Aug 2019*: The dog was taken to the vet for an unknown leg injury. It is unknown if any diagnostics or treatments were performed. 07 Oct 2019*: A dose was applied. 09 Oct 2019: The pet is shaking, barely walking, lethargic, for an unknown period of time. The owner also mentioned there are live fleas on the pet. No treatments have been given. The dog has had a similar reaction while on the product in the past and diagnosted with ocular seizures (see case 19US060269). The owner reported the dog becomes paralyzed if there are 3 or more ticks on her that clears up upon removal. There is history of Lyme disease. No medications are currently being given. There are 3 cats in the home on Seresto Flea Collars. The home is on a farming property and fleas and ticks are a known issue. No further medical information expected.
09-Oct-2019	UAE; 19US060199; IL; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	01-Mar-2019*	18-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019, the pet owner reported the following event for a female canine Shih Tzu mix , of further unknown signalment. Mar 2019* through 17 Sep 2019: The pet owner applied 1 dose of FRONTLINE PLUS DOG 23-44 LBS (M64702AL), in one spot, between the shoulder blades to the dog monthly. 18 Sep 2019*: The pet owner noticed the dog had fleas. She was seeing 2 to 3 fleas on the dog. 19 Sep 2019: The pet owner bathed the dog in an unknown pet shampoo. 30 Sep 2019:The most recent date of application. 1 Oct 2019: The pet owner was still seeing fleas on the dog and presented the dog to the veterinary clinic. The dog was treated with 1 dose of Capstar and 1 dose of Credelio. The dog currently has no fleas. The pet owner did not see fleas in the home, but she was being bitten by the fleas. The pet owner treated her home with Raid Flea Carpet Spray and washed blankets on an unknown date. The dog

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ED_005739D_00014391-00298

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											goes for walks once a day around 3 blocks and has access to a fenced in backyard for potty breaks. The backyard is fenced in with grass. The dog has Cushing's disease. The pet owner uses FRONTLINE PLUS DOG 23-44 LBS, monthly, seasonally for an unknown length of time. It is unknown if there are other pets in the home. No further medical information expected.
09-Oct-2019	UAE; 19US060218; -; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Yellow) **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 60 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Head and Shoulders shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Route not indicated / recommended)	01-Oct-2019	09-Oct-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019 the owner reported the following event for Abby, a 7 year old, 60 pound*, spayed female, Yellow Labrador Retriever. 1 Jan 2012* - 1 Sep 2019: The owner applied on vial of FRONTLINE PLUS DOG 45-88 LBS (S61810AX) topically down the back of the pet, monthly, year round. 1 Oct 2019: The owner applied FRONTLINE PLUS. 9 Oct 2019: The pet owner noticed 3 - 10 fleas* on the pet. The owner applied FRONTLINE PLUS. The pet has access to a fenced yard, where urban wildlife is present. the pet is also leash walked where stray cats are present. The pet was bathed with Head and Shoulders shampoo at an unknown time. There are no other pets in the home. The owner does not see fleas in the home. The pet is in good health and has no history of reactions. No further medical information expected.
09-Oct-2019	UAE; 19US060236; PA; U.S.A	**Species:** Feline **Breed:** Feline various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** 9 - 11 lbs	9	9	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	26-Sep-2019	09-Oct-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019, the pet owner reported the following event for 9 cats, 9-11 pounds, mixed breeds, with remaining signalment unknown. 2017*: The cats began receiving FRONTLINE PLUS CATS (S41404AW) monthly year round. The product was applied directly on the skin between the shoulder blades. 26 Jul 2019, 26 Aug 2019, 26 Sep 2019: The pet owner applied FRONTLINE PLUS CATS. 9 Oct 2019: The owner noticed a severe amount of fleas on the cats. The cats are indoor only. No treatments have been provided at home. The cat's current conditions are ongoing. These are the only pets in the household. No further medical information expected.
09-Oct-2019	UAE; 19US060245; PA; U.S.A	**Species:** Canine **Breed:** Rottweiler **Sex:** M **Sex qualifier:** - **Age:** 3.00 Year(s) **Weight:** 105 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 272MCG/652MG ; Phenobarbital; **Route:** unknown **Was the product used ok?:** Unknown	01-Sep-2019*	29-Sep-2019	4 Week(s)	D-B	Suspected Adverse Event: On 9 Oct 2019, the pet owner reported the following event for Euro, a 3 year old (born 6 Oct 2015) 105 pound intact male Rottweiler. 28 Sept 2019: The pet owner gave the dog a dose of HEARTGARD PLUS (272 mcg/227 mg) (8BC0112, Jan 2021). Dog has been on product since 2016*. 29 Sept 2019: The dog experienced a seizure where he fell over on his side kicking and foaming at the mouth. The dog recovered about an hour later. The dog has experienced seizures before, see cases 19US016934 and 19US016045. The dog is also on FRONTLINE PLUS DOG 89-132 LBS (lot unknown, package unavailable) and Phenobarbital on unknown dates. No further medical information expected. UPDATE 28 Oct 2019: Upon internal review, corrected expectedness on Assessment screen.

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ED_005739D_00014391-00299

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					
09-Oct-2019	UAE; 19US060269; -; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 62 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	07-Oct-2016*	09-Oct-2016*	2 Day(s)	D-B	Suspected Adverse Event: On 09 Oct 2019, the pet owner reported the following event for Gertrude, 62 pound, 1 year*, spayed female, Labrador Retriever mix. 05 Aug 2016*: The pet owner applied the contents of 1 vial FRONTLINE PLUS DOG 45-88 LBS (lot unknown/ package unavailable) topically to an unknown location for the first time monthly. 07 Oct 2016*: A dose was applied. 09 Oct 2016*: The pet started shaking, barely walking, lethargic, for 24 hours then was acting normally. These episodes occurred weekly until FRONTLINE was discontinued on an unknown date. The pet was taken to a veterinarian on an unknown date and diagnosed with ocular seizures. No further medical information expected.
09-Oct-2019	UAE; 19US060285; WI; U.S.A	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 24 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	01-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 9 Oct 2019, the owner reported the following event for a 24 pounds*, female, Terrier (Jack Russell)(all other signalments unknown). 1 Oct 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown, reporter not queried) was applied between the shoulder blades, by the pet owner. The owner stated that a unknown amount of minutes later the dog vomited and had diarrhea. 4 Oct 2019: The dog recovered. The dog did not present to the clinic and no treatment was provided. No further medical information is expected.
09-Oct-2019	UAE; 19US060290; MI; U.S.A	**Species:** Canine **Breed:** Setter (English) **Sex:** M **Sex qualifier:** - **Age:** 18.00 Month(s) **Weight:** 32 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019	09-Oct-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019, the owner reported the following event for Duke, a 32 pound, 18 month old (born 1 Apr 2018), intact male English Setter. 1 Oct 2019: 1 dose of FRONTLINE PLUS DOG 23-44 LBS (Lot Unknown, Package Unavailable) via unknown route and location. 9 Oct 2019: Duke was presented to the clinic and 5 engorged ticks were pulled off while reporter was in room. It is unknown if this was Duke's first dose of FRONTLINE PLUS. It is unknown if there are any other dogs in the home. The total number is unknown as caller left exam room to report case. Duke is a hunting dog that been in the woods everyday since at least 5 Oct 2019. No further information at this time.
09-Oct-2019	UAE; 19US060297; MD; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** - **Age:** 1.00 Year(s) **Weight:** 94 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	04-Oct-2019	3 Day(s)	D-C	Suspected Lack of Efficacy Claim: On 9 Oct 2019, the owner reported the following event for Ace, a 1 year old, 94 pound, intact German Shepherd Dog. 1 Oct 2019: One vial of FRONTLINE PLUS DOG 89-132 (S63307AX) was applied topically to the skin between the shoulder blades. 4 Oct 2019: Upon an annual exam the dog tested positive for Ehrlichia and was given Doxycycline as treatment. The dog has had ticks in the past once every few months that the owner removed. The dog is exposed to grass daily and is treated year round. No further information available. UPDATE 30 Oct 2019: The contact information was updated. No further information available.

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ED_005739D_00014391-00300

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
09-Oct-2019	UAE; 19US060308; IL; U.S.A	**Species:** Canine **Breed:** Siberian Husky **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 47 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dasuquin; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Oct-2019	05-Oct-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 09 Oct 2019, the pet owner reported the following event for Buttercup, 47 pounds, 9 year, spayed female, Siberian Husky. 03 Oct 2019: The owner applied the contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (J63803AR and M61905AR/ 01 Jan 2021) to the skin between the shoulder blades for the first time. The owner reported both lot numbers and unsure which was used. 05 Oct 2019: The owner found a small amount of live fleas while brushing the dog. This is the only pet in the home. No baths have been given. No fleas have been seen since, however the owner is unable to check the dog. The pet has no prior skin issues. The dog is currently taking Dasuquin. The dog is outside frequently. An opossum has been seen in the neighborhood. No further medical information expected.
09-Oct-2019	UAE; 19US060312; NJ; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** U **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Sep-2019	19-Sep-2019*	0 Day(s)	D-D	Suspected Adverse Event and Suspected Lack of Efficacy Claim: On 9 Oct 2019, the pet owner reported the following event for an 11 years old, 10 pound, Shih Tzu. 2018*: The pet began receiving FRONTLINE PLUS 5-22LBS (Lot unknown) (package unavailable), applied 1 vial topically between the shoulder blades monthly. 18 Sep 2019: Owner applied monthly dose. 19 Sep 2019*: Owner began seeing fleas. The pet began scratching a lot and developed an open wound above the application site on the neck. The owner has not been noticing fleas inside the home away from the pet. The environment is unknown. The pet has not presented to the veterinarian. No further medical information expected.
09-Oct-2019	UAE; 19US060340; MN; U.S.A	**Species:** Canine **Breed:** Terrier Breeds (500 Series) **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 40.000 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	01-Aug-2012*	15-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019 a pet owner called to report the following event in 3 dogs, Frank, a 40 pound*, 9 year old*, spayed female, Terrier mixed breed canine. 1 Aug 2012*: The dog began recieving FRONTLINE PLUS DOG 45-88LBS (F60913AR) in between the shoulders monthly with the most recent application on 1 May 2019*. There are 2 other dogs in the home in a larger weight class that also recieve FRONTLINE PLUS (see case 19US062971 for lack of efficacy). 15 May 2019*: The pet owner discovered the dog had at least 4 ticks present on them. The breed of tick was unknown. 1 Jun 2019* and Jul 2019*: The dog recieved another dose of FRONTLINE PLUS. 15 Jul 2019*: The pet owner discovered fleas on the dog, and the ticks were still being found daily on the dog. 1 Aug 2019*: The dog received another dose of FRONTLINE PLUS. 2 Aug 2019*: The pet owner continues to find fleas and ticks on the dog. The dog has access to a very wooded area in the back yard and frequent it. There is one other dog in the home that has been using Vectra 3D, and no fleas or ticks have been found on that dog. There are 2 other dogs reported in case 19US062971. FRONTLINE PLUS was discontinued. No further medical information expected.
09-Oct-2019	UAE; 19US060350; NY; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	27-Sep-2019	05-Oct-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019, the pet owner reported the following event for Mack, a male feline, of further unknown signalment. 27 Sep 2019: The pet owner applied FRONTLINE PLUS CATS (lot

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ED_005739D_00014391-00301

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					unknown, package unavailable), in one spot, between the shoulders, to the cat for the first time. 5 Oct 2019: The pet owner found an engorged tick on the cat, which she attempted to remove. 8 Oct 2019: The pet owner found 3 live ticks on the cat. The cat goes outside and has access to a lake and a marshy area that is near the home. The yard is not fenced in. The pet owner has a roommate with a strictly indoor cat and a dog. The roommate's cat has been treated with an unknown flea and tick treatment. It is unknown if the dog is on any flea or tick treatment. The cat is in good health and it is unknown if the cat currently has ticks. No further medical information expected.
10-Oct-2019	UAE; 19US060366; NY; U.S.A	**Species:** Canine **Breed:** Schnauzer (Miniature) **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 22 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Apr-2019	09-Oct-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the owner reported the following event for Bella, a female neutered, 22 pound, 9 year old, Miniature Schnauzer. 30 Sep 2019: One vial of the FRONTLINE PLUS DOG 5-22 LBS (S60302AL) was applied topically in between the shoulder blades by the owner. The owner purchased a 6 pack in April 2019. 10 Oct 2019: The owner noticed 1 flea on the dog after use of the product since April. The dog is indoor mostly and is walked on a leash for potty breaks and recreation. Fleas are not seen within the home and wildlife is not seen within the area. The owner uses the product year round since the pet was young. This is the first time she has seen a flea on the pet since using the product. This is the only pet within the home.No further medical information is expected.
10-Oct-2019	UAE; 19US060367; NY; U.S.A	**Species:** Canine **Breed:** Poodle (Standard) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 33 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Sep-2019	10-Oct-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, a pet owner reported the following event for Mabel, an 8 year old, 33 pound, spayed female Standard Poodle/Cocker Spaniel mix. 22 Sep 2019: The dog received 1 dose of FRONTLINE PLUS DOG 23-44 LBS (S61009AL) topically between the shoulder blades in one spot for the first time this year. 5 Oct 2019*: The owner found 2 live, attached ticks on the dog's neck and physically removed them. 10 Oct 2019: The owner found 1 live, attached tick on the dog's back leg and physically removed it. It is unknown if there are any other pets in the house. It is unknown what the outside environment is like. The dog has previously received FRONTLINE in 2015 and had Lyme disease, see case 19US060679. No further medical information expected.
10-Oct-2019	UAE; 19US060382; -; U.S.A	**Species:** Canine **Breed:** Border Collie **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 38 lbs	10	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Overdose)	03-Oct-2019	05-Oct-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, a pet owner reported the falling event for Indigo, a 4 year old, 38 pound, intact female Border Collie. 3 Oct 2019: The owner applied FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) for the first time. The owner does not recall seeing fleas. 5 Oct 2019: The owner saw flea dirt but did not see fleas on the dog. The dog lives on a far where to owner said there are a lot of fleas. There are 9 other dogs on the property who are being treated, no issues with the other dogs. All further details are unknown. No further medical information expected.
10-Oct-2019	UAE; 19US060386;	**Species:** Canine **Breed:** Chihuahua	1	1	0	**Product used:** FIPRONIL	11-Sep-2019	18-Sep-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the pet owner reported the following event for Puppy, a 3 year old, intact male, 6

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ED_005739D_00014391-00302

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	RI; U.S.A	**Sex:** M **Sex qualifier:** - **Age:** 3.00 Year(s) **Weight:** 6 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					pound, Chihuahua and Shih Tzu Mix. 11 Sep 2019: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (S61912AL). The product was applied directly on the skin between the shoulder blades. No fleas seen prior to application. 18 Sep 2019*: The owner noticed an unknown amount of fleas. The dog has access to a fenced in yard, with trees on the property, and access to under a deck area. The dog also goes on leash walks in the neighborhood. No treatments have been provided at home. The dog's current condition is ongoing. There is another dog in the household, who has been on FRONTLINE PLUS, and has fleas (See case 19US060427). No further medical information expected.
10-Oct-2019	UAE; 19US060392; ID; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019	10-Oct-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, animal owner reported the following event for an unknown signalment canine. 01 Aug 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 23-44 LBS (Lot unknown/ package unavailable) topically between the shoulder blades for the first time. No fleas were seen prior. 01 Sep 2019 - 01 Oct 2019: A dose was applied. 10 Oct 2019: The pet owner found several live fleas on the dog. The dog has access to a back yard through a doggy door. There are 2 cats in the home (See case 19US060396). The environment has not been cleaned and the dog has not been bathed. No further information expected.
10-Oct-2019	UAE; 19US060394; MA; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 48.2 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** RECOMBITEK LYME - 2126.R0; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jan-2019*	25-Sep-2019	8 Month(s) 3 Week(s)	D-C	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the clinic staff reported the following event for Maggie, 4 year old (4 Jun 2015), 48.2 pound, spayed female Large crossbreed canine. The dog was vaccinated with RECOMBITEK LYME (42227, 2 May 2020) 1ml, SC, in the left hind on 11 Oct 2016, 1 Nov 2016, 9 Nov 2017, and 27 Sept 2018. The dog tested negative for Lyme on 3 May 2018 and 28 Sept 2018. 25 Sept 2019: The dog tested positive for Lyme disease when it presented with sporadic lameness on a hind leg. A Quant C6 was submitted but results are unknown. The dog has also received FRONTLINE PLUS DOG 45-88 (lot and expiraiton unknown, package unavailable) on unknown dates. No further information available at this time. UPDATE 11 Oct 2019: Per veterinarian, the dog was lame on her left hind leg at presentation. Crepitus iin the left stifle was noted on physical exam. The Lyme test result 25 Sep 2019 was an Antech Accuplex test. The result was reported as positive for chronic exposure. Mondo has previously tested Lyme negative in 2017 on an Accuplex test. The Idexx quantitative C6 = <10 (<30 not significant, no treatment indicated). No further information expected.
10-Oct-2019	UAE; 19US060402; NC; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	01-Aug-2019	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the owner reported the following event for 3 canines(all other signalments unknown). 1 Aug 2019: The dogs started on FRONTLINE PLUS on a monthly basis. 1 Oct 2019: The most recent vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, reported not queried) was applied between the

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ED_005739D_00014391-00303

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					shoulder blades, by the pet owner. 2 Oct 2019*: The dog had a moderate amount of fleas. The owner did not bathed dogs. The owner is not seeing any flea activity in the household. The dogs have access to an unknown outside environment. No further medical information is expected.
10-Oct-2019	UAE; 19US060413; IA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Sep-2019*	25-Sep-2019*	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the pet owner reported the following event for a dog with unknown signalment. 1 Sep 2019*: The dog received FRONTLINE PLUS DOG (unsubstantiated) (lot unknown, package unavailable) with unknown purchase history. It is unknown if the dog has received the product previously. The product application details are unknown. Fleas were not seen prior to product application. 25 Sep 2019*: The pet owner began seeing fleas. 1 Oct 2019*: The monthly dose was applied. 10 Oct 2019: The owner is still noticing an unknown amount of fleas. The dog was bathed with an unknown dog shampoo. The pet owner lives on a large plot of land with wildlife present and the dog frequently goes camping with the family. The dog's current condition is ongoing. It is unknown if the dog presented to the veterinary clinic. It is unknown if treatments have been provided at home. It is unknown how many animals are in the household. Caller did not wish to answer any further questions. No further medical information expected.
10-Oct-2019	UAE; 19US060417; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Capstar; **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jul-2019*	08-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the owner reported the following event for an unknown feline (all other signalments unknown). Jul 2019*: Started on monthly doses of FRONTLINE PLUS CATS (lot unknown, reporter refused) unknown application, by the owner. The owner gave the cat a dose of Capstar prior to the application and also gives the product monthly. The cat had fleas prior to the application. Unknown date: Most recent dose of FRONTLINE was applied. The owner has started seeing fleas about 1 week after the application. The owner has seen the same problem after each application. The cat is an outdoor cat. The owner has mentioned having a heavy fleas infestation outside. The owner declined the report. No further medical information expected.
10-Oct-2019	UAE; 19US060427; RI; U.S.A	**Species:** Canine **Breed:** Beagle **Sex:** F **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 34 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Sep-2019	18-Sep-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the pet owner reported the following event for Lola, a 14 year old, spayed female, 34 pound, Beagle. 11 Sep 2019: The dog began receiving FRONTLINE PLUS DOG 23-44 LBS (T60209AL). The product was applied directly on the skin between the shoulder blades. 18 Sep 2019*: The owner noticed an unknown amount of fleas. The dog has access to a fenced in yard, with trees on the property, and access to under a deck area. The dog also goes on leash walks in the neighborhood. No treatments have been provided at home. The dog's current condition is ongoing. There is another dog in the household, who has been on FRONTLINE PLUS, and has fleas (See case 19US060386). No further medical information expected.
10-Oct-2019	UAE; 19US060428;	**Species:** Canine **Breed:** Canine	3	3	0	**Product used:** FIPRONIL	30-Sep-2019*	02-Oct-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the owner reported the following event for three 7-13 pound canines (all other

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* indicates Approximate date or weight.

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ED_005739D_00014391-00304

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; U.S.A	(unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 7 - 13 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					signalments unknown). 30 Sep 2019*: First dose of FRONTLINE PLUS DOG 5-22 LBS (T60214AL) was applied topically, between the shoulder blades, by the owner. The dogs did not have fleas prior to the application. 2 Oct 2019*: The owner started seeing fleas on the dogs. The owner is not seeing fleas in the home. The dogs go outside for potty breaks in a fenced in yard at an apartment complex. No further medical information expected.
10-Oct-2019	UAE; 19US060452; CA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 16 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Sep-2019	09-Oct-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019 the pet owner reported the following event for a 16 pound canine of unknown further signalment. 21 Sep 2019: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (lot number unknown, package unavailable), 1 vial topically, in between the shoulder blades for the first time. At the time of application there were no seen fleas on the canine. Prior to application, on the same day, the canine had been at the groomer. 09 Oct 2019: The canine spent an unknown amount of time at another pet owner's home. The pet owner noted fleas on the canine that evening. 10 Oct 2019: The pet owner is currently seeing a large amount of fleas on the pet but there are none inside the home. The canine spends the majority of the time inside the home with access to an outside lawn. There is a feline inside the home that is on Advantage and is not showing signs of fleas . No further medical information is expected.
10-Oct-2019	UAE; 19US060472; -; U.S.A	**Species:** Feline **Breed:** Feline various breeds **Sex:** X **Sex qualifier:** Neutered **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	08-Sep-2019*	15-Sep-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the pet owner reported the following event for 1 adult cats and 1 kitten of various breeds, mixed sexes, all other signalment unknown. 7 Sep 2019*: The owner brought home a new kitten from the United States Humane Association. 8 Sep 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (S40606AW) to the skin between the shoulder blades of each cat for the first time. It is unknown if fleas were seen prior to this dose. 15 Sep 2019*: The owner noticed an unknown amount of live fleas on both cats. 25 Sep 2019*: Both cats were taken to the veterinarian. The older cat was bathed and a different flea medication was applied . 10 Oct 2019: The owner reports continuing to see 1 or 2 live fleas on the kitten, but not the adult. These are the only pets in the home. The cats are indoors only. The older cat has a history of flea allergies. No fleas are seen in the home. The environment is unknown. No further medical information expected.
10-Oct-2019	UAE; 19US060477; NY; U.S.A	**Species:** Canine **Breed:** Canine Other **Sex:** M **Sex qualifier:** - **Age:** 7.00 Year(s) **Weight:** 140 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	01-Apr-2019*	15-Apr-2019*	N/A	D-C	Suspected Adverse Event: On 10 Oct 2019, the owner reported the following event for Leo, 7 years old, 140 pounds, Intact male, Swiss Mountain Dog. Apr 2019: The dog started on FRONTLINE PLUS(product unsubstantiated). The owner stated that dog had a seizure this month but was unsure of date. July 2019: Another dose of the product was applied. The dog had a seizure this month after the application. The dog present to clinic. Bloodwork and a physical exam was performed. No treatment was

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ED_005739D_00014391-00305

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					provided. 5 Oct 2019: The most recent vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown, package unavailable) was applied between the shoulder blades, by the pet owner. 10 Oct 2019: The dog had a seizure. The dog was lethargic after the seizure. UPDATE: On 11 Oct 2019, the pet owner provided the lot number for FRONTLINE PLUS DOG 89-132 LBS (R62114AR). No further medical information is expected.
10-Oct-2019	UAE; 19US060478; MI; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 89 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Sep-2019	07-Oct-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, The pet owner reported the following event for a 10 year old*, 89 pound*, neutered male, Golden Retriever. 15 Jan 2014* - 15 Sep 2019: The pet owner applied one vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown, package unavailable) topically between the shoulder blades, monthly year round. 26 Sep 2019 - 28 Sep 2019: The owner took the pet hunting in a heavily wooded area. 7 Oct 2019: The owner took a fully engorged tick off the pet. The species of tick is unknown. 9 Oct 2019: The owner took a fully engorged tick off the pet. the species of tick is unknown. 10 Oct 2019: The owner took a fully engorged tick off the pet. The species of tick is unknown. It is unknown if the ticks were alive when the owner took them off the pet. The pet has access to a yard with a large variety of urban wildlife, including coyote and deer. The owner takes the pet on hunting trips. The pet is bathed with an unknown pet shampoo monthly. The pet is in good health. There is a 10 week old puppy in the home not currently on flea and tick preventative. No further medical information expected.
10-Oct-2019	UAE; 19US060501; SC; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 60 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Sep-2017*	01-Aug-2019*	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the pet owner reported the following event for a 60 pound* canine of further unknown signalment. Sep 2017*: The canine began receiving one vial of FRONTLINE PLUS DOG 45-88 LBS (FL+) (lot unknown; package unavailable) applied topically between the shoulder blades. One vial has since been applied monthly around the seventeenth, year-round, in like fashion and fleas were never present at the times of application. 17 Jul 2019*: One vial of FL+ (S62111AL) was applied at which time, no fleas were seen. 1 Aug 2019*: The reporter began seeing an unknown volume of fleas on the dog who stays outside on a 3 acre wooded plot of land. 17 Aug 2019* and 17 Sep 2019: A large volume of fleas were present each time one vial of FL+ was applied. Unknown dates: The reporter bathed the canine with Dawn dish detergent to remove a large volume of fleas seen on its body. Presently, the reporter continues to find a large volume of fleas on the dog and has seen blood on the patient where the fleas were biting. There are three smaller dogs in the home that also have fleas despite respective FRONTLINE PLUS use. Please see case 19US060720 for details. No further medical information expected.
10-Oct-2019	UAE; 19US060507; PA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair	1	1	0	**Product used:** FIPRONIL 10%/S	10-Sep-2019	25-Sep-2019	1 Day	D-D	Suspected Lack of Efficacy Claim and Adverse Event: On 10 Oct 2019, the pet owner reported the following event for Cosmo, a 14 month old, 10 pound, neutered male, Domestic Longhair.

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ED_005739D_00014391-00306

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		(Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 Month(s) **Weight:** 10 lbs				METHOPRENE 12% SPOT ON **Other products used:** Unknown Flea and Tick Shampoo; **Route:** dental **Was the product used ok?:** No (Treatment / vaccination program not respected)					5 Sep 2019*: Fleas were noticed prior. 10 Sep 2019 : The patient got their doses of FRONTLINE PLUS CATS(lot unknown, package unavailable). The cat has never had FRONTLINE before this. It was applied between the shoulder blades. 11 Sep 2019: The owner noticed fleas were still present. 24 Sep 2019: Per veterinary recommendation, another dose of FRONTLINE PLUS was applied before 30 days. 25 Sep 2019: The owner was still seeing fleas on the animal. The pet does not go outside. The pet is showing hair loss at application site. The owner bathes the pet once a week unknown flea and tick shampoo, but exact dates are unknown. There are no fleas in the home, and no fleas on the owner. The patient's current condition is ongoing. There is a total of 1 canine and 1 feline in the household. The canine is also on FRONTLINE PLUS, but it is not having issues with fleas at this time. No further medical information expected.
10-Oct-2019	UAE; 19US060515; MO; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	08-Aug-2019*	10-Oct-2019	9 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, a pet owner reported the following event for Lizzy, an approximately 7 year old, 8 pound, spayed female Domestic Longhair. 2018*: The cat began receiving monthly applications of FRONTLINE PLUS CATS (S41004AW) topically between the shoulder blades in one spot during the summer months. 8 Jun 2019*: The cat started receiving monthly applications of FRONTLINE PLUS CATS for the first time this year. The owner is unsure if the cat had fleas prior to the application. 8 Aug 2019* and 8 Sep 2019*: The cat received FRONTLINE applications. The owner noticed the cat scratching a few days after the applications but did not check to see if the cat had fleas. 6 Oct 2019: The cat was bathed in Dawn detergent. 8 Oct 2019: The cat received another application of FRONTLINE. 10 Oct 2019: The owner combed the cat and saw an unknown amount of live fleas. The owner claims that she was getting bit by something in Jul and used a flea spray on the carpets. The cat does go outside some. There are no other pets in the home. The owner has recently seen some flea dirt on the bed. The cat had previously reacted to FRONTLINE in Jul 2019, see case 19US061167. No further information expected.
10-Oct-2019	UAE; 19US060518; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 54 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Jul-2019	30-Jul-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the pet owner reported the following event for Peaches, a 54 pound, female canine, of further unknown signalment. Jul 2019*: The pet owner found an unknown number of fleas on the dog. 16 Jul 2019, 12 Aug 2019, and 12 Sep 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S62408AX) topically between the shoulder blades. 19 Sep 2019*: The dog was bathed with dawn. 30 Sep 2019*: The dog was bathed with an unknown pet shampoo. 30 Jul 2019* to 10 Oct 2019: The owner continues to see 2-6 fleas on the dog daily and combs daily. Dog is scratching from the fleas daily. 07 Oct 2019: The dog presented to the veterinarian for itching. The dog was treated with prednisone and the veterinarian stated that FRONTLINE does not work. The dog is indoor and goes outside to use the bathroom. There is

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ED_005739D_00014391-00307

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											also a cat in the home, reference case 19US060521. Call ended before further details were obtained due to owner being unreceptive. No further medical information expected.
10-Oct-2019	UAE; 19US060521; -; U.S.A	**Species:** Feline **Breed:** Siamese **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Jul-2019	30-Jul-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the pet owner reported the following event for a siamese of further unknown signalment. Jul 2019*: The pet owner found an unknown number of fleas on the cat. 16 Jul 2019, 12 Aug 2019, and 12 Sep 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CAT (S40901AW) topically between the shoulder blades. 30 Jul 2019* to 10 Oct 2019: The owner continues to see 2-6 fleas on the cat daily and combs daily. Cat is scratching from the fleas daily and has scabs on its' neck. The cat is indoor only. There is also a dog in the home, reference case 19US060518. Call ended before further details were obtained due to owner being unreceptive. No further medical information expected.
10-Oct-2019	UAE; 19US060523; WI; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019*	03-Oct-2019*	2 Day(s)	D-D	Suspected Adverse Event: On 10 Oct 2019, the pet owner reported the following event for Shiro, a 5 year old*, 15 pound*, neutered male Domestic Shorthair. 1 Oct 2019*: The cat began receiving FRONTLINE PLUS CATS (S41103) for the first time. The product was applied directly on the skin between the shoulder blades. Fleas were not seen prior to product application. 3 Oct 2019*: The cat lost hair at the application site, resulting in a thumbprint-sized bald spot. The bald skin is intact. The cat has not presented to the veterinary clinic. No treatment has been provided at home. 10 Oct 2019: The cat's current condition is ongoing. The cat previously received FRONTLINE GOLD FOR CATS with no previous adverse effects. No further medical information expected.
10-Oct-2019	UAE; 19US060530; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2017*	02-Jan-2017*	1 Day(s)	D-A	Suspected Adverse Event: On 10 Oct 2019 the pet owner reported the following event for a canine of unknown signalment. Unknown date: The pet owner had applied an unknown amount of FRONTLINE PLUS (unsubstantiated) (lot unknown, package unavailable) in an unknown location on the dog. The dog died of unknown causes. It is unknown if a necropsy was performed. Specific details are unknown. The dog has received FRONTLINE PLUS DOG previously on unknown dates with no issues noted. The pet owner called in to inquire about FRONTLINE PLUS DOG expiration dating and mentioned her previous dog that had died in passing. No further medical information expected.
10-Oct-2019	UAE; 19US060537; VA; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 25 - 41 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	01-Oct-2019	09-Oct-2019*	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the pet owner reported the following event for 2 dogs, 3 year old, spayed females, 25-41 pounds, mixed breeds. 2016*: The dogs began receiving FRONTLINE PLUS DOG 23-44 LBS (S61401AL) monthly seasonal use. The product was applied directly on the skin between the shoulder blades. 1 Oct 2019: The most recent date of application. 9 Oct 2019*: The owner noticed a small amount of fleas on the dogs. The dogs have access to a fenced in yard and do go on

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ED_005739D_00014391-00308

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** Yes					leash walks. No treatments have been provided at home. The dogs' current conditions are ongoing. These are the only pets in the household. The client is wondering what pet shampoos she can use with the FRONTLINE PLUS. No further medical information expected.
10-Oct-2019	UAE; 19US060554; -; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 70 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	08-Oct-2019	09-Oct-2019	1 Day(s)	D-D	Suspected Adverse Event and Suspected Lack of Efficacy Claim: On 10 Oct 2019, the pet owner reported the following event for a 70 pound*, female, canine of further unknown signalment. Unknown date: The reporter began finding an unknown number of fleas on the dog. 8 Oct 2019: The reporter applied one vial of FRONTLINE PLUS DOG 45-88 LBS (FL+) (lot unknown; reporter refused) topically between the dog's shoulder blades at which time, an unknown volume fleas were seen; however, shortly after application, the reporter blotted an unknown volume of product off of the dog because the product was sitting on top of the dog's short hair coat. To keep the product from running off of the pet, she blotted an unknown volume of it off. Ultimately, the reporter felt the full volume of FL+ was too much and the entire application would not be needed to be effective for her dog. 9 Oct 2019: She observed an oily spot either on the dog's skin and/or hair coat where FL+ had been applied. 10 Oct 2019: The reporter saw two live fleas on the patient who was also pruritic at the time she saw the two fleas. On approximately the same date, she's found what suspects to be an infected flea bite on the dog. The only further description she could provide was that the affected area looked similar to a large, infected closed comedo. Presently, it's unknown if treatment has been given for the ongoing flea issue or for the clinical signs reported. There is a second dog in the home that weighs around 24 pounds* that received an unknown application of Advantage on 8 Sep 2019. At the time of said application, an unknown volume of fleas were seen on that dog. Both dogs go outside on walks and the reporter lives near a forest. This is the extent of information that could be obtained. No further medical information expected.
12-Nov-2019	UAE; 19US060557; WI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 85 - 100 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn dish detergent; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Sep-2019	16-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim and Adverse Event: On 10 Oct 2019 the pet owner reported the following event for two canines weighing 85-100 lbs each of unknown further signalment. 6 Sep 2019: The pet owner applied FRONTLINE PLUS DOG 89-132 LBS (S62006BX), 1 vial topically, in between the shoulder blades for each canine. A small amount of fleas were seen on the pets for an unknown amount of time prior to application. 16 Sep 2019*: The pet owner was still seeing fleas so she applied another dose to each canine. 18 Sep 2019*: Both canines were bathed with Dawn dish soap. Currently, the pet owner is still seeing a small amount of fleas on the two canines but none inside the home. The two canines spend the majority of the time inside the home with access to an outside lawn. There are two felines inside the home that are not on a flea product that also have fleas. No further medical information is expected. UPDATE 23 Oct 2019: Case changed to an inquiry due to preexisting fleas and less than 3 months administered. UPDATE 12 Nov 2019: Per the pet owner: 6 Oct 2019*: Each dog received one vial of FRONTLINE PLUS DOG 89-132 LBS (FL+) applied topically between the shoulder

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ED_005739D_00014391-00309

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											blades. It's unknown if fleas were present at the time of product application. Unknown date: An unknown duration after FL+ application, the reporter noticed both dogs were extremely pruritic even though fleas were not seen on either one of them. She also noticed both canines chewing their skin, especially above the base of their tails and have since developed localized alopecia secondary to pruritus and chewing the skin over the affected area. 4 Nov 2019*: Each dog received one vial of FL+ applied topically between the shoulder blades. It's unknown if fleas were present at the time of product application. Unknown date: An unknown duration after FL+ application, the reporter noticed both dogs were extremely pruritic even though fleas were not seen on either one of them. She also noticed both
02-Oct-2019	UAE; 19US060560; MD; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 17 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jan-2017*	14-Apr-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy: On 2 Oct 2019, a pet owner reported the following event for Milo, a 2 year old*, 17 pound*, neutered male, Domestic Shorthair feline. 1 Apr 2019*: The cat received FRONTLINE PLUS CATS (R41105AW) between the shoulder blades. The pet owner applies flea prevention monthly year round and has been using this since 2017* on the cat. There are also 6 dogs in the home that also receive FRONTLINE PLUS (see case 19US058640 and case 19US058637). 15 Apr 2019*: The owner discovered the cat had fleas. The owner reports the cat is indoor only. The 6 dogs in the home have fleas as well and have access to a large back yard that is surrounded by foliage and trees. The owner has not stopped seeing fleas all summer and notices they are worse at the end of the month. The owner lives in a rural neighborhood and wildlife frequents the area. The owner has been purchasing the FRONTLINE PLUS from Ebay since the beginning of this year. It is unknown if the owner is seeing fleas in the home. No further medical information expected.
10-Oct-2019	UAE; 19US060568; IN; U.S.A	**Species:** Canine **Breed:** Boxer **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 97 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	24-Sep-2019	10-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On the 10 Oct 2019, a pet owner reported the following event for Vicious, a 97 pound, 9 year old, spayed female, Boxer. 24 May 2019: The dog was started on monthly FRONTLINE PLUS DOG 89-132 LBS (S60906AR) with 1 dose applied topically between the shoulder blades. The owner applies the product seasonally and this was the first application of the season. The owner was not seeing any fleas in his home or on the dog. The dog has access to a fenced in backyard with grass, trees and bushes. The dog is mostly indoors. There are no other pets in the home. Jul 2019: The owner missed giving a monthly dose. 24 Aug 2019: The owner noticed a couple of fleas on the dog so he purchased a 3 pack and applied 1 dose to the dog. 24 Sep 2019: The most recent dose of FRONTLINE was applied to the dog. The owner noticed the dog had a large amount of fleas on her. 10 Oct 2019: The owner noticed that the dog still has a large amount of fleas on her. He sprayed the backyard with an unknown pesticide. The issue is ongoing. No further medical information expected.
07-Oct-2019	UAE; 19US060582; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	01-Jan-2017*	06-Oct-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Oct 2019, the owner reported the following for an unknown feline, all other signalment unknown. 30 Sep 2019: One vial of the FRONTLINE PLUS FOR CATS (lot

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ED_005739D_00014391-00310

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					unknown, package unavailable was applied topically in between the shoulder blades by the owner. The owner purchased a 3 pack in at an unknown date. 6 Oct 2019: The owner did not notice fleas but large amount of flea dirt after using the product consistently. This is the first time the owner has noticed this on the pets. The cat is outdoor only but has open acreage and a barn. Fleas are not seen within the home and it is unknown if wildlife is seen within the area. The owner also has dog that is also having issues with flea dirt see case 19US059545.No further medical information is expected.
10-Oct-2019	UAE; 19US060588; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the owner reported the following event for an unknown feline (all signalments unknown). Unknown date: Cat started on monthly doses of FRONTLINE PLUS CATS (lot unknown, reporter refused) unknown application, by the owner. On an unknown date most recent dose was applied. An unknown amount of time later, the owner started seeing ticks on the cat. Some ticks were engorged, some were not attached, some were alive. The owner removed the ticks once observed. Cat is indoor and outdoor. No further medical information expected.
10-Oct-2019	UAE; 19US060598; PA; U.S.A	**Species:** Canine **Breed:** Spaniel (Brittany) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 90 - 93 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	11-Jun-2019	01-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019 a pet owner reported the following event for three Brittany Spaniels weighing between 90 to 93 pounds each and other signalment unknown. 11 Jun 2019: Owner applied FRONTLINE PLUS DOG 89-132 LBS (P61809) in an unknown manner, most recently prior to seeing fleas. Jul 2019*: Owner started noticing dogs scratching more, bathed them with an unknown product, and was seeing more than 10 fleas on the dogs. The owner has continued to see fleas on the dog since Jul 2019*. The owner is not seeing fleas in the home. The owner has been using the product monthly on the dogs for 3 years and has not previously had a problems with fleas. The pet owner would not let me ask him probing questions, or find out more information. He stated he only wanted to give the lot number so we would know the batch was bad and refused to give further details.
10-Oct-2019	UAE; 19US060601; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	10-Oct-2019*	10-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, a pet owner reported the following event for an unknown amount of canines with unknown signalment. Unknown Date: The dogs were administered FRONTLINE PLUS DOG (product unsubstantaited)(lot unknown, package unavailable) and the dogs had fleas. Unknown Date: The dogs still have fleas. All further details are unknown as owner was irate. The owner also has cats that hare having the same issue, see case 19US060610. No further medical information expected.
10-Oct-2019	UAE; 19US060607;	**Species:** Canine **Breed:** Retriever	1	1	0	**Product used:** FIPRONIL	06-Jul-2019	13-Jul-2019*	N/A	D-C	Suspected Adverse Event: On 10 Oct 2019 The pet owner reported the following event for Lexi, a 3 year old*, 78 pound*,

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ED_005739D_00014391-00311

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	CA; U.S.A	(Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 78 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					spayed female, Golden Retriever. 6 Jul 2019: The owner applied one vial of FRONTLINE PLUS 45-88 LBS (S60715AX) topically to an unknown location for the first time. 13 Jul 2019*: The pet had a seizure. It is unknown if treatments were given. 23 Aug 2019: The owner applied FRONTLINE PLUS to the pet. 28 Aug 2019*: The pet had a seizure. It is unknown if treatments were given. 1 Oct 2019: The owner applied FRONTLINE PLUS to the pet. 4 Oct 2019: The pet had a seizure and was taken to the veterinarian, it is unknown if any treatments were given. The pet has not had seizure prior to the application of FRONTLINE PLUS. The pet was healthy prior to application and has no history of reactions. The pet is not currently on any medications and has recovered. No further medical information is expected.
10-Oct-2019	UAE; 19US060610; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	10-Oct-2019*	10-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, a pet owner reported the following event for an unknown amount of felines with unknown signalment. Unknown Date: The cats were administered FRONTLINE PLUS CATS (lot unknown, package unavailable) and the cats had fleas. Unknown Date: The cats still have fleas. All further details are unknown as owner was irate. The owner also has dogs that hare having the same issue, see case 19US060601. No further medical information expected.
10-Oct-2019	UAE; 19US060620; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	03-Oct-2019*	08-Oct-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the pet owner reported the following event for 1 male canine, all other signalments unknown. 03 Oct 2019*: The owner applied FRONTLINE PLUS DOG (product unsubstantiated/ lot unknown/ package unavailable) in a manner of unknown usage. It is unknown if this was the first use. 05 Oct 2019*: The owner took the pet hunting in the woods. 08 Oct 2019*: The owner found an unknown species of engorged tick. No further information was obtained as the reported disconnected the call before other information could be obtained. No further medical information expected.
11-Oct-2019	UAE; 19US060635; -; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 1.50 Year(s) **Weight:** 26 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Sep-2018*	11-Oct-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the owner reported the following event for Lumpy, a 26 pound, 1.5 year old*, spayed female Labrador Retriever mix. May 2018*: Lumpy started on FRONTLINE PLUS DOG 23-44 LBS (S6230AW), topically in between the shoulder blades. 30 Sep 2019: The most recent dose was applied. 11 Oct 2019: Lumpy was scratching more than usual and the owner's child found 1 flea on the dog. Lumpy is considered an indoor/outdoor dog that goes outside for occasional walks, hikes, and potty breaks. There were no fleas seen prior to product use. The pet gets baths every 2-3 weeks with a dog shampoo and does not have a history of skin issues. There are no other pets in the home. The owner has been treating monthly with FRONTLINE since May 2018*. No further information

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Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											at this time.
11-Oct-2019	UAE; 19US060642; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	10-Oct-2019	11-Oct-2019	1 Day(s)	D-D	Suspected Adverse Event: On 10 Oct 2019, the pet owner reported the following event for a canine of unknown signalment. Unknown date: The canine became pruritic. 10 Oct 2019: An unknown duration following onset of pruritus, the reporter applied one vial of unknown FRONTLINE PLUS (lot unknown; package unavailable) (product unsubstantiated) topically in an unknown location on the dog. An unknown duration following unknown FRONTLINE PLUS application, the reporter found the dog to still be as pruritic as when the product was applied. 11 Oct 2019: In addition to the ongoing pruritus, the reporter is seeing the canine scratch and chew its body so much so that hotspots are beginning to develop. The reporter assumes fleas are responsible for his dog's symptoms, but he cannot confirm if fleas are present on the dog. Presently, treatment has not been administered, though the reporter was on his way to the veterinarian to pick up an unknown antibiotic to give the patient for the skin issues. The reporter would not provide any additional information pertaining to the event. No further medical information expected.
11-Oct-2019	UAE; 19US060643; -; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 20 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Aug-2008	28-Sep-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019 the pet owner reported the following event for an 11 year old (birth date unknown), 20 pound, female Small crossbred canine of unknown further signalment. 28 Aug 2008*: Started on FRONTLINE PLUS DOG 5-22 LBS (S62405SX) (invalid lot number), 1 vial topically, in between the shoulder blades once monthly. 28 Aug 2019: The pet owner applied one dose to the canine. 23 Sep 2019: A small number of fleas were discovered on the pet. 28 Sep 2019: The most recent dose was applied. 11 Oct 2019: Currently, the pet owner is still seeing a small amount of fleas on the pet but none inside the home. The canine spends the majority of the time inside the home and is leash walked outside. There are no other pets inside the home. No further information is expected.
11-Oct-2019	UAE; 19US060649; -; U.S.A	**Species:** Canine **Breed:** Siberian Husky **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	06-Oct-2019*	07-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for 2 Siberian Huskies of further unknown signalment. UNKNOWN DATE: The pet owner found a couple of fleas on the dogs. 06 Oct 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) topically between the shoulder blades. The owner continued to see fleas on the dogs. It is unknown if this was the first dose received. 06 Oct 2019* to 11 Oct 2019: The owner continues to see a couple of fleas on the dogs daily. The dogs scratch from the fleas daily. There are no other pets in the home. The dogs are indoor and outdoor. There is carpet in the home. The dogs have not been bathed and there are no fleas in the home. The owner sees wildlife in the environment. No further medical information expected.
11-Oct-2019	UAE; 19US060651; MI; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	03-Mar-2019*	10-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for Daisy, 13 pound, 11 year, spayed female, Mixed Breed. 03 Mar 2019*: The owner applied the contents of 1 vial

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ED_005739D_00014391-00313

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 13 lbs				9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					FRONTLINE PLUS 5-22 LBS (lot unknown/ package unavailable) topically to an unknown location monthly for the first time of the year. 03 Oct 2019*: A dose was applied. 10 Oct 2019: The owner found 2 fleas on the pet and removed them. 11 Oct 2019: No fleas have been seen. This is the only pet in the home. The pet is outside for short periods of time in a fenced in backyard. Outdoor cats and opossums are known to travel through the yard. The pet has a history of skin allergies and is on an unknown antihistamine. The owner reports the pet is bathed with Top Paw Baking Soda shampoo and conditioner and bedding is cleaned every other month, last bath was on an unknown date. No fleas have been seen in the home. No further medical information expected.
11-Oct-2019	UAE; 19US060652; WI; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 10.4 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** DELMOPINOL 21 MG ORAL CHEWABLE TABLET; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Sep-2019*	24-Sep-2019*	23 Day(s)	D-D	Suspected Adverse Event: On 11 Oct 2019, the clinic staff reported the following event for Toby, 12 year old (10 Apr 2007), 10.4 pound, neutered male, Small crossbreed canine. 1 Sept 2019*: An unknown amount of FRONTLINE PLUS (product unsubstantiated) (lot unknown, package unavailable) was applied topically. It is unknown if the pet received the product before. 23 Sept 2019*: One chew of ORAVET DENTAL HYGIENE CHEWS S (05072021, 7 May 2021) was administered orally for the first time. 24 Sept 2019*: The dog began experiencing diarrhea. The pet did not present to the clinic and no treatment was provided. 11 Oct 2019*: The dog recovered. No further medical information is expected.
11-Oct-2019	UAE; 19US060656; KY; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019	10-Oct-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On date, reporter called and reported the following for a canine of unknown signalment. 1 Oct 2019: Pet owner applied FRONTLINE PLUS DOG 5-22 LBS (unsubstantiated) (lot unknown, reporter refused). An unknown volume per animal via an unknown route at an unknown location. 10 Oct 2019: Pet owner noticed two fleas on the canine. The pet owner bathed the dog in a Dawn dish detergent. It is unknown if they presented to a veterinary clinic. Their current condition is unknown. It is unknown what environment the canine frequents. It is unknown if the owner bathes the canines. There is one other dog in the household, who is on FRONTLINE PLUS for an unknown amount of time, and no fleas have been noted on that dog. This is the extent of information known as caller refused to report. No further medical information expected.
11-Oct-2019	UAE; 19US060661; TX; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** X **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 90 lbs	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	02-Jul-2019*	10-Oct-2019*	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct the owner reported the following event for 4 Labrador Retrievers, 3 years* to 13 years*, 90 lbs*, 1 female spayed and 3 male neutered canines. 1 Jul 2019*: The pet owner noticed 1 or 2 fleas* on the pets. 2 Jul 2019*: The pet owner applied 1 vial of FRONTLINE PLUS DOG 89-132 LBS (S62006BX) topically between the shoulder blades to each pet for the first time. 1 Aug 2019*: The owner notices an unknown amount of fleas on all

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ED_005739D_00014391-00314

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** Yes					the pets. 2 Aug 2019* - 2 Oct 2019*: The pet owner applied FRONTLINE PLUS to each pet monthly. 10 Oct 2019: The pet owner continues to notice 30* to 40* fleas on the pets. The owner bathed the pets in Dawn dish soap and an unknown flea and tick shampoo. The pets were treated with Adams flea spray on unknown dates. The pets live outside and have no access into the home. There is urban wildlife present as the home is in a rural area. The pets are in good health and have no history of reactions. No further medical information expected.
11-Oct-2019	UAE; 19US060663; OH; U.S.A	**Species:** Canine **Breed:** Dachshund **Sex:** F **Sex qualifier:** Neutered **Age:** 18.00 Month(s) **Weight:** 11 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2018*	26-Sep-2019	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for Alle, a 18 month old, 11 pound, spayed female, Dachshund. 1 Sep 2019: The patient got their monthly dose of FRONTLINE PLUS DOG 5-22 LBS(lot unknown). The animal gets FRONTLINE every month, and has since 2018*. The owner purchased a 6 pack this past purchase. It was applied between the shoulder blades. 26 Sep 2019: The owner noticed fleas on the animal. They were not seen prior to this day. The pet goes outside daily. The pet is showing no skin issues, but is itching from the fleas. The owner does not bathe the pet. There are no fleas in the home, and no fleas on the owner. The patient's current condition is ongoing. There is a total of 1 canine and 2 felines in the household. The 2 cats both use FRONTLINE and are not having flea issues. No further medical information expected.
11-Oct-2019	UAE; 19US060676; NJ; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 7.9 lbs	7	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Rabies vaccine, unknown; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)	14-Sep-2019*	10-Oct-2019	26 Day(s)	D-D	Suspected Adverse Event: On 11 Oct 2019 the owner reported the following event for Margaret Meade, a 13 year old*, 7.9 lb, spayed female, Domestic Shorthair. 14 Sep 2019*: The pet owner applied half of a vial of FRONTLINE PLUS CATS (lot unknown). The owner had lots R41005AW and S40601AXR and the time of application, but cannot be confirmed which lot was used on the pet. Unknown Date: The pet went to the veterinarian for an unknown rabies vaccine given in an unknown location by an unknown route. 10 Oct 2019: The pet owner noticed a bald patch between the pets shoulder blades, where the FRONTLINE is applied. The pet has been receiving FRONTLINE PLUS its entire life (2006*), but on an unknown schedule on unknown dates. The pet was in good health prior to application and has no history of reactions. The pet has not been to the veterinarian for this issue and has had no treatments. No further medical information expected.
10-Oct-2019	UAE; 19US060679; NY; U.S.A	**Species:** Canine **Breed:** Poodle (Standard) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 33 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	01-Sep-2015*	15-Sep-2015*	2 Week(s)	D-C	Suspected Lack of Efficacy Claim: On 10 Oct 2019, a pet owner reported the following event for Mabel, a 4 year old, 33 pound, spayed female Standard Poodle/Cocker Spaniel mix. Unknown Date 2015*: The dog began receiving monthly applications of FRONTLINE PLUS DOG 23-44 LBS (Lot Unknown, Package Unavailable) topically between the shoulder blades in one spot. Unknown Date 2015*: The dog tested positive for Lyme disease on an unknown test. The dog was treated with an unknown antibiotic. It is unknown if the dog was symptomatic. It is unknown if any additional testing was performed. The dog started to receive unknown Lyme vaccinations after she

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ED_005739D_00014391-00315

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					tested Lyme positive. No further medical information expected. UPDATE 23 Oct 2019: The dog had another case reported, see 19US060367.
11-Oct-2019	UAE; 19US060683; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 16.00 Year(s) **Weight:** 7 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Sep-2019	28-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019 a pet owner reported the following event for a 7* pound, 16 year old, female spayed Domestic Shorthair. 27 Sep 2019: Owner applied FRONTLINE PLUS CATS (S40601RX) to the skin on the animal's neck for the first time. 28 Sep 2019*: The owner is seeing 2 to 3 live fleas on the cat. 10 Oct 2019: Owner found 2 live fleas on the cat. The cat lives inside only. The cat does not receive baths. There are two dogs in the home who live on a different level of the home , are on FRONTLINE PLUS, and do not have fleas. The owner has seen fleas in the home on the level of the home where the cat lives. The owner has not treated the home with pesticides. No further medical information expected.
11-Oct-2019	UAE; 19US060684; OH; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 80 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	09-Oct-2019*	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the owner reported the following event for a 80 pound canine, with remaining unknown signalment. Unknown Date: The pet started on FRONTLINE PLUS DOG 45-88 (Lot Unknown, Package Unavailable), topically in between the shoulder blades. 1 Oct 2019: The most recent dose was applied. 9 Oct 2019*: The owner saw a moderate amount of fleas on the pet. The dog is considered an(indoor/outdoor dog that goes outside for occasional walks and potty breaks. There were no fleas seen prior to product use. The does not get baths on a regular basis, but does get Dawn soap baths on a PRN basis. The dog does not have a history of skin issues. There are 4 other cats in the home that are also on FRONTLINE FOR CATS (lot unknown, package unavailable) that also have fleas (Please see case 19US060695). The owner has been treating monthly with FRONTLINE since an unknown date for years. No further information at this time. UPDATE 14 Oct 2019: Per owner: Cats were on Advantage and not FRONTLINE FOR CATS. No further information at this time.
11-Oct-2019	UAE; 19US060703; OH; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jun-2019*	01-Sep-2019*	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for Oliver, a 2 year old*, 10 pound*, neutered male, Domestic Shorthair. 1 Jun 2019*: The cat began receiving FRONTLINE PLUS CATS (lot unknown, package unavailable) monthly. The product was applied directly on the skin between the shoulder blades. It is unknown if fleas were seen prior to product application. 2 Jun 2019*: The pet owner reports seeing an unknown number of fleas on the cat. The cat is indoor only. 1 Jul 2019* and 1 Aug 2019*: The most recent dates of application. 1 Sep 2019*: The pet owner switched to a different unknown flea/tick control product. The cat's current condition is ongoing. This the only pet in the household. No further medical information expected.
11-Oct-2019	UAE; 19US060705; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	17-Sep-2019*	11-Oct-2019	24 Day(s)	D-D	Suspected Adverse Event: On 11 Oct 2019 an animal owner reported the following event with Buddy, an intact stray cat. All other signalment unknown. 17 Sep 2019*: The feline was administered FRONTLINE PLUS

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* indicates Approximate date or weight.

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ED_005739D_00014391-00316

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: - **Age:** - **Weight:** Unknown				12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					CATS (lot, expiration unknown. Package unavailable) between the shoulder blades for the first time. It is unknown if there were fleas at time of administration. 11 Oct 2019: The feline is scratching. No fleas seen. The feline has access to outdoors. There are no other pets in the household. No further information provided nor expected.
11-Oct-2019	UAE; 19US060707; -; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 8.5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Trifexis; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	21-Sep-2019	10-Oct-2019	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for a 12 year old, 8.5 pound, female, Shih Tzu of further unknown signalment. Unknown dates: The canine received unknown doses of Trifexis. 21 Sep 2019: The reporter applied an unknown volume of unknown FRONTLINE PLUS (lot unknown; reporter refused) (product unsubstantiated), topically in an unknown location on the dog. It's unknown if she's previously received this product and fleas were not present at the time of application, nor has she ever had fleas in her twelve years of living. 10 Oct 2019: That night, the reporter found 13 fleas on the canine. Presently, the flea issue is ongoing. The reporter refused to provide any additional information regarding the reported issue and any relevant details. No further medical information expected.
11-Oct-2019	UAE; 19US060709; VA; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Month(s) **Weight:** 18.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	22-Apr-2019*	02-Oct-2019*	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for Gracie, an 18.0 pound, 8 month old, spayed female miniature Australian Shepherd. 22 Apr 2019*: The pet owner applied 1 dose of FRONTLINE PLUS DOG 5-22 LBS (S60714RX), topically, in an unknown location, to the dog for the first time. 22 Sep 2019: The most recent date of application. 2 Oct 2019*: The pet owner noticed fleas on the dog. 27 Sep 2019* and 6 Oct 2019: The pet owner bathed the dog in a pet approved pet shampoo. The pet owner is currently seeing 1 to 5 fleas on her dog. The dog goes outside mainly for potty break in a fenced in yard. The pet owner has not seen any fleas in the home and there are no other pets in the home. No further medical information is expected.
11-Oct-2019	UAE; 19US060713; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	07-Sep-2019*	11-Oct-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, a pet owner reported the following event for a canine of unknown signalment. Unknown Date: The dog started FRONTLINE PLUS DOG (product unsubstantiated)(lot unknown, package unavailable) monthly. The dog had fleas. 7 Oct 2019: The owner applied FRONTLINE PLUS. The dog had fleas. 11 Oct 2019: The owner is seeing fleas. The dog does go outside. All further details unknown. No further medical information expected.
11-Oct-2019	UAE; 19US060716; IN; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON	01-Oct-2019*	06-Oct-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for Troy and Tobias, 3 and 12 year old, neutered males, 12 pounds, Domestic Shorthairs. 1 Jul 2019*, 1 Aug 2019*, 1 Sep 2019*: The cats began receiving FRONTLINE PLUS CATS (lot unknown, package unavailable)

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ED_005739D_00014391-00317

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Neutered **Age:** 3.00 Year(s) **Weight:** 12 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					monthly. The product was applied directly on the skin between the shoulder blades. 1 Oct 2019*: The most recent date of application. 6 Oct 2019: The owner noticed an unknown amount of fleas on the cats. The fleas have also been seen in the home and are biting the humans. The cats are indoor only. No treatments have been provided at home. The cats' current conditions are ongoing. There is also a dog in the household, who is on FRONTLINE PLUS, and has fleas (See case 10US060732). No further medical information expected.
10-Oct-2019	UAE; 19US060720; SC; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 8 - 11 lbs*	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Sep-2017*	01-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the pet owner reported the following event for three canines weighing between 8 pounds* and 11 pounds* and are of further unknown signalment. Sep 2017*: Each of the three dogs began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (lot unknown; package unavailable) applied topically between the shoulder blades. One vial has since been applied to each dog monthly around the seventeenth, year-round, in like fashion and fleas were never present at the times of application. 17 Jul 2019*: Each canine received one vial of FL+ (S63009BL) at which time, no fleas were seen. 1 Aug 2019*: The reporter began seeing an unknown volume of fleas on all three dogs. 17 Aug 2019* and 17 Sep 2019: A large volume of fleas were seen on each dog when they each received one vial of FL+ applied as described above. Unknown dates: The reporter saw fleas jumping off of the dogs. She subsequently bathed the dogs with Dawn dish detergent to remove the large volume of fleas present. Presently, the reporter continues to find a large volume of fleas on the dogs. There is a larger dog that stays outside and despite respective FRONTLINE PLUS application, also has fleas. Please see case 19US060501 for details. The three dogs reported in this case stay primarily indoors but do go outside for bathroom breaks and have access to a wooded 3 acre plot of land. There have been no visiting animals in the home. No further medical information expected.
11-Oct-2019	UAE; 19US060724; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	08-Oct-2019*	11-Oct-2019*	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for a canine of further unknown signalment. UNKNOWN DATE: The pet owner found 2-3 fleas on the dog. 08 Oct 2019*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown, package unavailable) topically between the shoulder blades. 11 Oct 2019*: The owner found 2-3 fleas on the dog. There are no other pets in the home. There is carpet in the home. The dog is indoor and goes outside to use the bathroom. The owner is not seeing fleas in the home. No further medical information expected.
11-Oct-2019	UAE; 19US060732; IN; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Yellow) **Sex:** F **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	01-Oct-2019*	06-Oct-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for Saco, an 11 year old, 85 pound, spayed female, Labrador Retriever. 1 Jul 2019*, 1 Aug 2019*, 1 Sep 2019*: The dog began receiving FRONTLINE PLUS CATS (lot unknown, package unavailable)

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ED_005739D_00014391-00318

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Neutered **Age:** 11.00 Year(s) **Weight:** 85 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					monthly. The product was applied directly on the skin between the shoulder blades. 1 Oct 2019*: The most recent date of application. 6 Oct 2019: The owner noticed an unknown amount of fleas, and bites on the dog's body. The fleas have also been seen in the home and are biting the humans. The dog does have access to an open area, with trees and brush on the property. The dog does go on leash walks and to the dog park. The dog presented to the veterinary clinic. It is unknown if diagnostics have been performed. Treatments have been initiated with an unknown flea/tick product. The dog's current condition is ongoing. There are also two cats in the household, who are on FRONTLINE PLUS, and have fleas (See case 10US060716). No further medical information expected.
11-Oct-2019	UAE; 19US060734; NY; U.S.A	**Species:** Canine **Breed:** Samoyed **Sex:** M **Sex qualifier:** - **Age:** 9.00 Month(s) **Weight:** 45.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	02-Oct-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 11 Oct 2019, the pet owner reported the following event for Ivan, a 9 month old, 45.0 pound, intact male Samoyed. 1 Oct 2019: The pet owner applied 1 dose of FRONTLINE PLUS DOG 45-88 LBS (P63007AR), between the shoulders in one spot, for the first time. 2 Oct 2019*: A pet tracker notified the pet owner that the dog had an increase of scratching. 10 Oct 2019: The pet owner bathed the dog in an unknown pet approved shampoo. While bathing the dog, she noticed that the application site was red, irritated and bloody. 11 Oct 2019: The dog presented to the veterinary clinic and was treated with cefpodixime, dexamethasone injection, Entederm ointment, prednisolone tablets and VetraSeb CK wipes. The dog is currently not recovered. No further medical information expected.
19-Nov-2019	UAE; 19US060737; TX; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 75 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Oct-2019*	19-Nov-2019	5 Week(s)	D-D	Suspected Lack of Efficacy Claim: On the 11 Oct 2019, a pet owner reported the following event for Bandit, a 75 pound, 4 year old, spayed female, German Shepherd. 15 Aug 2019: The pet owner noticed that the dog was scratching and she noticed that there were about 3 fleas on the dog. The owner gave the dog 1 dose of Capstar. The owner purchased and applied for the first time in 2 years the FRONTLINE PLUS DOG 45-88 LBS (S6181AX) 1 dose, topically between the shoulder blades. There are no other animals in the home. The dog is indoor/outdoor. She has access to a fenced in backyard with grass. The dog spends the majority of her time indoors. 15 Sep 2019: The owner applied the most recent dose of FRONTLINE to the dog. The owner saw a couple of fleas and gave another dose of Capstar 11 Oct 2019: The pet owner noticed that the dog had 1 flea on the base of her tail. The issue is ongoing. No further medical information expected. UPDATE 24 Oct 2019: Case changed to an inquiry due to preexisting fleas and less than 3 months administered. UPDATE 19 Nov 2019: The pet owner called in with an update on case. 15 Oct 2019*: The pet owner applied the product. 19 Nov 2019: The pet onwer is still noticing an unknown amount of fleas. The pet owner has also been using FRONTLINE PLUS CATS on her cats, with a report of fleas also (see case 19US067815). No further medical information expected.

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ED_005739D_00014391-00319

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
11-Oct-2019	UAE; 19US060752; IL; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** - **Age:** 7.00 Year(s) **Weight:** 70 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown homeopathic tick preventative; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Aug-2019	05-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019 the owner reported the following event for Corky a 7 year old*, 70 pound*, intact male, Labrador Retriever and Poodle cross. Jan 2012* through 4 Oct 2019: The owner applied one vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) topically between the shoulder blades on pet monthly and year round. 5 Oct 2019 through 7 Oct 2019: The owner has found one tick each day on the pet and removed them. The pet is walked in the woods, where the owner notices on the walks there are 20* or more ticks on the pet each walk on unknown dates. The pet has a history of seizures and it is unknown if he is on any medication for the condition. It is unknown if the pet is bathed. No further medical information expected. UPDATE 19 Nov 2019: Per the owner, she has discontinued the use of FRONTLINE PLUS DOG for the month of November and started to use a unknown homeopathic tick preventative on unknown dates. The owner has also stopped walking the pet in the woods and no longer notices any ticks on the pet. The pet is recovered. The owner requested to see if the product was foreign label and gave the lot number of S62202AX, the lot is a valid US labeled lot for a 6 pack of FRONTLINE PLUS DOG 45-88 LBS. No further medical information expected.
11-Oct-2019	UAE; 19US060761; -; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** U **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 110 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	01-Sep-2019	11-Oct-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the owner reported the following event for a 4 year old, 110 pound, Put Bull canine (all other signalments unknown). 1 Sept 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (L65004AR) was applied between the shoulder blades. 11 Sept 2019: The owner started to notice a medium amount of fleas for the first time. 1 Oct 2019: Another vial was applied. The issue persisted. 6 Oct 2019: The owner applied another vial. 11 Oct 2019: The flea issue is still ongoing. The dog has access to a fenced in yard. The owner bathes the dog twice a month with dog shampoo. The dog has used the product year round since 2015* with no issue. There are no other pets in the home. No further medical information is expected.
11-Oct-2019	UAE; 19US060766; MD; U.S.A	**Species:** Canine **Breed:** Border Collie **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Month(s) **Weight:** 12 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not	04-Sep-2019*	27-Sep-2019*	23 Day(s)	D-D	Suspected Lack of Efficacy: On 11 Oct 2019 the owner reported the following event for Segan a, 6 month old*, 12 pound*, neutered male, Border Collie. 28 Aug 2019*: The puppy was brought into the home. 4 Sep 2019*: The owner applied 1 vial of FRONTLINE PLUS 5-22 LBS (S61902AL) topically between the shoulder blades for the first time. 27 Sep 2019*: The owner noticed 20 - 30 fleas* on the pet and applied one vial of FRONTLINE PLUS to the pet. 11 Oct 2019: The owner continues to see fleas on the pet. The pet has access outside to a grass yard where urban wildlife is present. The pet is leash walked to the same spot each day. There are 2 other dogs in the home see case 19US060949 and 19US060901 . It is unknown if the pet was bathed. The pet was in good health prior to application and has no history of reactions. No further medical information expected.

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ED_005739D_00014391-00320

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						respected)					
11-Oct-2019	UAE; 19US060816; MA; U.S.A	**Species:** Canine **Breed:** Bichon Frise **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Month(s) **Weight:** 11.4 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Oct-2019	11-Oct-2019	0 Day(s)	D-C	Suspected Adverse Event: On 11 Oct 2019, the pet owner reported the following event for Bella, 11.4 pounds, 8 month (12 Feb 2019), spayed female, Bichon Frise mix. 11 Oct 2019: The owner applied the contents of 1 vial FRONTLINE PLUS 5-22 LBS (lot unknown/ package unavailable) to the skin between the shoulder blades for the first time. 1 hour late, the pet was on her back, breathing slower, and unresponsive to the owner for 5 minutes. When the owner turned to leave the room, the pet did get up and follow. The owner stated the pet seems slightly lethargic, but otherwise normal 1 hour after the initial event. The owner reported the skin at the application site looks normal. This is the only pet in the home. The owner reported the pet did have a history of skin irritation after using SimpleGard topical flea medication. The pet was taken to the vet and washed with Dawn dish soap. No further medical information expected.
11-Oct-2019	UAE; 19US060841; CA; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 11 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	24-Sep-2018*	25-Sep-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for Milo, a 9 year old, 11 pound, neutered male, Yorkshire Terrier and Poodle Mix. 2018*: The pet received FRONTLINE PLUS DOG 5-22 LBS (S61017AL) monthly during the Summer months for an unknown amount of time. The product was applied directly on the skin between the shoulder blades. 24 Sep 2019: The most recent date of application. 25 Sep 2019: The owner noticed an unknown amount of fleas. It is unknown what environment the canines frequent. The dog presented to the veterinary clinic, but no treatments were done. 1 Oct 2019: The pet owner bathed the pet in an unknown flea/tick shampoo. The dog's current condition is ongoing. There is also one cat in the household, who was treated with FRONTLINE PLUS, and has fleas (See case 19US060849). The owner declined to provide additional information. No further medical information expected.
11-Oct-2019	UAE; 19US060849; CA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	24-Sep-2019	25-Sep-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for Smokey, a 5 year old, 15 pound, neutered male, Domestic Shorthair. 24 Sep 2019: The pet received FRONTLINE PLUS CATS (lot unknown, package unavailable) for the first time. The product was applied directly on the skin between the shoulder blades. 25 Sep 2019: The owner noticed an unknown amount of fleas. The cat is indoor only. 1 Oct 2019: The pet owner bathed the pet in an unknown flea/tick shampoo. The cat's current condition is ongoing. There is also one dog in the household, who was treated with FRONTLINE PLUS, and has fleas (See case 19US060841). No further medical information expected.
11-Oct-2019	UAE; 19US060850; -; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Yellow) **Sex:** M **Sex qualifier:** - **Age:** 7.00 Year(s) **Weight:** 80 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown	01-May-2019	01-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, a pet owner reported the following event for Max, a 7 year old, 80 pound, intact male Yellow Labrador. 1 May 2019: The owner applied FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) for the first time of the season. The dog did not have fleas. 1 Aug 2019*: The owner applied the most recent dose and saw fleas. The dog goes outside and hunts. All further details are unknown as owner not receptive. No further medical information

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ED_005739D_00014391-00321

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					expected.
11-Oct-2019	UAE; 19US060853; -; U.S.A	**Species:** Canine **Breed:** Cavalier King Charles **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2019	11-Oct-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for Radar, a 3 year old, 15 pound, neutered male, Cavalier King Charles Spaniel. Aug 2019 (unknown dates): Radar boarded at a day care facility. 1 Sep 2019: Immediately after finding a flea on the canine, the reporter applied one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (S62405AX) topically between Radar's shoulder blades. It cannot be confirmed whether or not the single flea was removed prior or post FL+ application. Unknown dates: On five sporadic dates throughout Sep 2019, Radar attended that same day care facility where he was with other dogs. 4 Oct 2019*: A second vial of FL+ was applied in the manner previously described. It's unknown if fleas were seen at the time of product application. 11 Oct 2019*: The reporter is finding a small volume of fleas on the canine. Presently, he's not finding any fleas in the home. There are no other resident animals nor have there been any visiting animals in the home. The reporter wonders if Radar may have gotten fleas when he was boarding, but ultimately he cannot be sure. It's unclear where the dog typically goes outside for bathroom breaks because he lives with the reporter out in the middle of the ocean on a boat. No further medical information expected.
11-Oct-2019	UAE; 19US060854; WV; U.S.A	**Species:** Canine **Breed:** Hound Breeds (200 Series) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 60 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Sep-2019	01-Oct-2019*	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for Remy, a 3 year old, 60 pound, neutered male, Hound. Oct 2018*: The dog began receiving FRONTLINE PLUS DOG 45-88 LBS (S61810AX) monthly year round. The product was applied directly on the skin between the shoulder blades. 5 Aug 2019: The pet owner applied product. 11 Sep 2019: The pet owner applied product. 1 Oct 2019*: The owner is still noticed a large amount of ticks. The dog has access to a mostly fenced in large yard, with trees and brush on the property. No treatments have been provided at home. The dog's current condition is ongoing. 4 Oct 2019: The most recent date of application. 11 Oct 2019: The pet owner is still noticing a large amount of ticks. There is one other canine in the household, who is also on FRONTLINE PLUS, with no ticks. No further medical information expected.
11-Oct-2019	UAE; 19US060859; NY; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	01-Jan-2019*	11-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 11 Oct 2019 the owner reported the following issue for Mischa, a 6 year old*, 5 pound*, spayed female, Domestic Shorthair. 1 Jan 2019* - 1 Sep 2019*: The owner applied one vial of FRONTLINE PLUS CATS (S40210CW) topically between the shoulder blades once monthly, year round. 11 Sep 2019: The owner noticed the pet was itching, but did not see any fleas on the pet. 1 Oct 2019*: The owner applied FRONTLINE PLUS to the pet. 2 Oct 2019*: The pet owner noticed the pet was very itchy, she took the pet to the veterinarian. The veterinarian noticed an unknown amount of fleas on the pet. It is unknown if the pet was

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ED_005739D_00014391-00322

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					treated. 11 Oct 2019: The pet continues to scratch. The pet has access outside, where there are woods with urban wildlife present. The pet is not bathed. The owner does not see fleas in the home and is not being bit by fleas. The pet was in good health and has no history of reactions. There are no other pets in the home. the pet has been receiving FRONTLINE PLUS year round since 2017*. No further medical information expected.
11-Oct-2019	UAE; 19US060860; SC; U.S.A	**Species:** Canine **Breed:** Shar Pei **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 45.000 lbs	4	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	05-May-2019	19-May-2019	0 Day(s)	D-D	Suspected Adverse Event and Lack of Efficacy: On 11 Oct 2019, the pet owner reported the following event for a Shar Pei mix, 45 pounds, all other signalments unknown. 05 May 2019: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 45-88 LBS (F63106AX) to the skin between the shoulder blades for the first time after seeing an unknown amount live fleas on the dog. 19 May 2019: The owner applied another dose after continuing to see the same amount of live fleas on the dog. The pet vomited grass an unknown amount of time after treatment. The owner did not wish to provide any additional details on this case. A total of 4 dogs were on the product on these dates (19US060852). No further medical information expected.
11-Oct-2019	UAE; 19US060863; IA; U.S.A	**Species:** Canine **Breed:** Schnauzer (Miniature) **Sex:** M **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** 18 - 20 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-May-2019*	25-Sep-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the pet owner reported the following event for 2 Dogs, 4 and 14 years old, 18 and 20 pounds, intact males, Miniature Schnauzers. Unknown date: The dogs began receiving FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable) monthly seasonally starting in an unknown month. The product was applied directly on the skin between the shoulder blades. 1 Jul 2019*, 1 Aug 2019*, 22 Sep 2019*: The product was applied. No fleas were seen prior to product application. 25 Sep 2019: The owner noticed a small amount of fleas on the dogs. The dogs have access to a fenced in yard, with trees and brush on the property. No treatments have been provided at home. The dogs' current conditions are ongoing. These are the only pets in the household. No further medical information expected.
11-Oct-2019	UAE; 19US060870; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 23 - 30 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	24-Aug-2019*	28-Sep-2019*	5 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the owner reported the following event for three 23-30 pound canines (all other signalments unknown). 24 Aug 2019*: First dose of FRONTLINE PLUS DOG 23-44 LBS (S61401AL) was applied topically between the shoulder blades by the owner. The owner was not seeing fleas prior to the application. 28 Sep 2019*: The owner started seeing fleas on the dogs. 29 Sep 2019: Most recent dose of FRONTLINE was applied. The owner continues to see fleas on the dogs. The owner is not seeing fleas in the home. The dogs go outside for potty breaks in a fenced in yard with 1 tree and a deck. The owner had a visiting pet that was not treated in the home around the time the first dose of FRONTLINE was applied. The owner also has 3 cats that are being treated with FRONTLINE (see case 19US060871). No further medical information expected.

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ED_005739D_00014391-00323

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
11-Oct-2019	UAE; 19US060871; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 10 lbs	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	24-Aug-2019*	28-Sep-2019*	5 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019, the owner reported the following event for three approx. 10 pound felines (all other signalments unknown). 24 Aug 2019*: First dose of FRONTLINE PLUS CATS (lot unknown, package unavailable) was applied topically between the shoulder blades by the owner. The owner was not seeing fleas prior to the application. 28 Sep 2019*: The owner started seeing fleas on one of the cats. 29 Sep 2019: Most recent dose of FRONTLINE was applied. The owner continues to see fleas on one cat. The owner is not seeing fleas in the home. The cats are strictly indoor. The owner had a visiting pet that was not treated in the home around the time the first dose of FRONTLINE was applied. The owner also has 3 dogs that are being treated with FRONTLINE (see case 19US060870). No further medical information expected.
09-Oct-2019	UAE; 19US060874; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	05-Oct-2019*	06-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Oct 2019, the pet owner reported the following event for a canine of unknown signalment. It is unknown if owner saw fleas prior to FRONTLINE dose. 5 Oct 2019*: The patient got their dose of FRONTLINE PLUS DOG (Unsubstantiated)(lot unknown, reporter refused). It is unknown if the animal has had FRONTLINE prior to this. It unknown where it was applied. 6 Oct 2019*: The owner noticed fleas. The pet does go outside. It is unknown if the pet is bathed or showing any skin issues. It is unknown if there are fleas in the home or on the owner. The patient's current condition is ongoing. It is unknown how many animals in are in the household in total. No further medical information expected.
14-Oct-2019	UAE; 19US060887; IL; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 15 - 18 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Contraindication per label)	01-Oct-2019	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019 the owner reported the following event for 2 Yorkshire Terriers, 12 to 13 years old*, 15 to 18 pounds*, neutered males. 1 Oct 2019*: the owner noticed a large amount of fleas and applied one vial of FRONTLINE PLUS DOG 5-22 LBS(S61203AX) topically between the shoulder blades. The pet owner continued to see fleas on the pet a few hours* after application and bathed the pets in Dawn dish soap. 2 Oct 2019*: The owner continues to see fleas and bathes the dogs in Dawn dish soap 14 Oct 2019: The pet owner continues to see an unknown amount of fleas on the pets. The pets are bathed every day in Dawn dish soap and apple cider vinegar. The pets have access to a grass yard and neighbor dogs. As per the pet owner, the neighbors dog had a flea infestation. The pets were in good health prior to the application. There are no other pets in the home. No further medical information expected.
14-Oct-2019	UAE; 19US060892; CA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** 8 - 13 lbs	11	11	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products	01-Oct-2019*	10-Oct-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for eleven, 8 pound* to 13 pound*, mixed (gender), felines of further unknown signalment. 15 Sep 2019*: The reporter noticed a very small volume of fleas on an unknown number of felines. 1 Oct 2019*: Each of the 11 felines received one vial of FRONTLINE PLUS CATS (FL+) (S40210) applied topically between their shoulder blades by the reporter. At the time of FL+

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ED_005739D_00014391-00324

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** Yes					application, approximately four of five cats had a very small volume of fleas present and it's unknown if any of the 11 cats have previously received FL+. 10 Oct 2019*: Because the reporter was finding one or two fleas on each cat, every cat was bathed with an unknown, all natural cat shampoo to remove the fleas present. Presently, all 11 cats have one or two fleas on their bodies. Fleas are not being found in the home and all of the linens in the house have been washed. Of the 11 felines, 7 are fosters who have been in the home for a long though unknown period of time. There have been no visiting animals in the home. All 11 felines are indoor only because there are coyotes outside. No further medical information expected.
14-Oct-2019	UAE; 19US060896; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 20 - 23 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	01-Oct-2019	02-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for 2 canines, weighing 20 to 23, all other signalments unknown. 01 Jan 2018*: The owner applied the contents of 1 vial FRONTLINE PLUS (S61009AL) to the skin between the shoulder blades of each monthly for the first time. 01 Oct 2019: The owner applied a dose. 02 Oct 2019: The dogs started scratching themselves. 05 Oct 2019*: The owner noticed 1-2 live fleas on the pets and bathed with Dawn dish soap. The owner reported seeing fleas in the water during bathing. 13 Oct 2019: The owner saw 1-2 live fleas on each pet. There are no other pets in the home. The dogs go outside in the yard for short periods of time. The yard is treated with Home Defense. The dogs have no prior skin issues or flea history. The owner is unsure if there is any urban wildlife in the neighborhood. No fleas have been seen in the home. No further medical information expected.
11-Oct-2019	UAE; 19US060901; MD; U.S.A	**Species:** Canine **Breed:** Irish Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 26 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Jul-2019*	27-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019 the owner reported the following event for Dez, a 6 year old*, 26 pound*, neutered male, Irish terrier cross. Jan 2017* through Jul 2019*: The owner applied one vial of FRONTLINE PLUS DOG 23-44 LBS (S61009AL) topically between the shoulder blades monthly, year round. 27 Aug 2019*: The owner noticed an unknown amount of fleas on the pet. The owner applied FRONTLINE PLUS to the pet. 11 Sep 2019: The owner noticed 12 or more fleas* on the pet and bathes him with an unknown pet approved shampoo. 27 Sep 2019: The owner continues to notice an unknown amount of fleas on the pet. The owner applies FRONTLINE PLUS. 11 Oct 2019: The owner continues to notice fleas on the pet. No fleas are seen in the home. The pet has access outside to a grass yard, where urban wildlife is present. The pet was in good health prior to the application and has no history of reactions. There are 2 other dogs in the home see case 19US060949 and 19US060766. no further medical information expected.
14-Oct-2019	UAE; 19US060903; GA; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	05-Oct-2019*	11-Oct-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event on Saint Francis, a 7 year old, 70.0 pound, neutered male, German Shepherd Dog. Oct 2019*: The pet owner bathed the dog in an unknown pet approved shampoo and treated the home with Precor. She had not seen any fleas on her dog.

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ED_005739D_00014391-00325

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 7.00 Year(s) **Weight:** 70.0 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					5 Oct 2019*: The pet owner applied 1 dose of FRONTLINE PLUS DOG 45-88 LBS (S61810AX), between the shoulder blades and about 4 inches down, for the first time to the dog. 11 Oct 2019*: Approximately 6 days after application, the dog began to experience pruritus and the pet owner noticed 3 to 4 fleas on the dog. The pet owner is still seeing fleas on the dog. The dog goes outside in a fenced in yard with grass and trees. There are no fleas being seen in the home. No further medical information expected. UPDATE 28 Oct 2019: The pet owner reported the following update. 23 Oct 2019: The dog presented to the veterinary clinic still experiencing fleas. The veterinarian advised the pet owner to treat the dog with a different product. There are no other pets in the home. No further medical information expected.
14-Oct-2019	UAE; 19US060907; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 9 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Apr-2019*	23-Sep-2019*	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019 the owner reported the following event for Smokey, a 6 year old*, 9 pound*, spayed female cat of unknown breed. Feb 2018*: The pet was adopted. Apr 2019*: It is unknown if fleas were seen prior to application. Apr 2018* through Aug 2019*: The owner applies one vial of FRONTLINE PLUS CATS (S40601AX) topically between the shoulder blades, monthly year round. 23 Sep 2019*: The owner applied FRONTLINE PLUS to the pet. The owner noticed a large amount of fleas on the pets face. 14 Oct 2019: the pet owner continues to see an unknown amount of fleas on the pet. The pet is an outdoor only pet and lives in a barn on the property. The pet has no access to the home. There is a large amount of urban wildlife present. The pet is not bathed. The pet is in good health and has no history of reactions. No further medical information expected.
14-Oct-2019	UAE; 19US060911; MN; U.S.A	**Species:** Canine **Breed:** Doberman **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 78 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Apr-2019	14-Oct-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 14 Oct 2019, a pet owner reported the following event for Maximus, a 78 pound, 4 year old, neutered male, Doberman. 1 Apr 2019: The pet owner noticed that the dog had about 20 fleas on him. She purchased and applied for the first time 1 dose of FRONTLINE PLUS DOG 45-88 LBS (R62310AR), topically between the shoulder blades. The owner applies flea and tick seasonally and this was the first dose of the season that was applied. The dog is indoor/outdoor. He has access to a fenced in backyard with grass trees and bushes. The dog spends the majority of his time indoors. There is 1 cat in the home with the same issue. 1 May -1 Oct 2019: The owner applied 1 dose topically to the dog. 14 Oct 2019: The pet owner is still seeing a large amount of fleas on her dog. The issue is ongoing. The same issue is ocurring to the cat see case 19US060913. No further medical information expected.
14-Oct-2019	UAE; 19US060913; MN; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other	01-Apr-2019	14-Oct-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 14 Oct 2019, a pet owner reported the following event for Snickers, a 10 pound, 10 year old, spayed female, Domestic Shorthair. 1 Apr 2019: The pet owner noticed that the cat had about 20 fleas on her. She purchased and applied for the first time 1 dose of FRONTLINE PLUS CATS (S40210BW), topically between the shoulder blades. The owner applies flea and tick seasonally and

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ED_005739D_00014391-00326

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 10.00 Year(s) **Weight:** 10 lbs				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					this was the first dose of the season that was applied. The cat is indoor/outdoor. She has access to a fenced in backyard with grass trees and bushes. The cat spends the majority of her time indoors. There is 1 dog in the home with the same issue. 1 May -1 Oct 2019: The owner applied 1 dose topically to the cat. 14 Oct 2019: The pet owner is still seeing a large amount of fleas on her cat. The issue is ongoing. The same issue is ocurring to the dog see case 19US060911. No further medical information expected.
14-Oct-2019	UAE; 19US060920; NY; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	12-Oct-2019	13-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for a dog with unknown signalment. 12 Oct 2019: The dog received FRONTLINE PLUS DOG (unsubstantiated) (lot unknown, package unavailable). It is unknown if the dog has previously received product. Product application details are unknown. Fleas were seen a few days prior to product application, and the dog was scratching starting at that time. 13 Oct 2019: The owner is still noticing an unknown amount of fleas. The dog's excursion details are unknown. 14 Oct 2019: The pet owner used a flea comb to remove all the fleas, but the dog is still scratching. It is unknown if the dog presented to the veterinary clinic. It is unknown if treatments have been provided at home. The dog's current condition is ongoing. It is unknown if there are any other animals in the household. Caller did not wish to answer any further questions. No further medical information expected.
10-Oct-2019	UAE; 19US060925; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	13-Sep-2019	10-Oct-2019	27 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Oct 2019, the pet owner reported the following event for a canine of unknown signalment. It is unknown if fleas were noted prior to the dose of FRONTLINE. 13 Sep 2019: The patient got their dose of FRONTLINE PLUS DOG (Unsubstantiated)(lot unknown, reporter refused). It is unknown if the animal had FRONTLINE before this, It is unknown where on the animal it was applied. 10 Oct 2019: The owner noticed fleas, as the animal was itching due to them. It is unknown if the animal goes outside, it is unknown if the animal gets bathed, and it is unknown if the owner is seeing fleas in the home or on her person. The patient's current condition is ongoing. It is unknown how many animals are in the household. The owner declined further inquiry as she was primarily calling to see if she should go ahead an give another dose early. No further medical information expected.
14-Oct-2019	UAE; 19US060927; IL; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	15-Jul-2019	16-Sep-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the owner reported the following event for a feline (all other signalments unknown). 15 July 2019: The cat started on FRONTLINE PLUS on a monthly basis. 15 Sept 2019: The most recent vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) was applied between the shoulder blades, by the pet owner. 16 Sept 2019*: The cat had fleas. The cat does not get bathed. The owner is noticing flea activity in the household. The cat is indoor/outdoor. The owner vacuumed the home for fleas.

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ED_005739D_00014391-00327

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					No further medical information is expected.
14-Oct-2019	UAE; 19US060947; FL; U.S.A	**Species:** Canine **Breed:** Eskimo (Spitz) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 17 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	06-Oct-2019	07-Oct-2019	1 Day(s)	D-D	Suspected Adverse Event: On 14 Oct 2019 a pet owner called to report the following event in Juliet, a 17 pound, 6 year old, spayed female, American Eskimo and Pomeranian mixed breed dog. 1 Oct 2019*: The pet owner discovered the dog had fleas. 6 Oct 2019: The pet owner applied FRONTLINE PLUS 5-22LBS (Lot unknown, package unavailable) to the dog for the first time. 7 Oct 2019: The pet was experiencing hair loss and skin irritation. She was also very itchy all over. 8 Oct 2019*: The dog was seen by a veterinarian for continued hair loss and itching. The veterinarian treated the dog with an unknown antibiotic, steroids, and topical antiseptic spray. 14 Oct 2019: It is unknown if the dog has recovered. It is unknown if the dog still has fleas. No further medical information expected. UPDATE15 Oct 2019: Per medical records, the dog was seen by a veterinarian on 7 Oct 2019 and given 1.5mL of DexSp in an unknown way, 1.0mL of Convenia in an unknown way, and prescribed Betagen spray. No further medical information expected.
11-Oct-2019	UAE; 19US060949; MD; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 51 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Jan-2017*	27-Aug-2019*	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Oct 2019 the owner reported the following event for Baxter, a 8 year old*, 51 pound*, neutered male, Labrador retriever and German Shepherd dog cross. Jan 2017* through Jul 2019*: The owner applied one vial of FRONTLINE PLUS DOG 45-88 LBS (S61101AR) topically between the shoulder blades monthly, year round. 27 Aug 2019*: The owner noticed an unknown amount of fleas on the pet. The owner applied FRONTLINE PLUS to the pet. 11 Sep 2019: The owner noticed an unknown amount of fleas on the pet and bathes him with an unknown pet approved shampoo. 27 Sep 2019: The owner continues to notice an unknown amount of fleas on the pet. The owner applies FRONTLINE PLUS. 11 Oct 2019: The owner continues to notice fleas on the pet. No fleas are seen in the home. The pet has access outside to a grass yard, where urban wildlife is present. The pet was brought to the veterinarian due to hair loss and scabs on the back and hind end, and diagnosed with flea allergy dermitis. The pet is currently being treated with unknown antibiotics and and unknown amount of prednisone. The pet was in good health prior to the application and has no history of reactions. There are 2 other dogs in the home see case 19US060901 and 19US060766. No further medical information expected.
14-Oct-2019	UAE; 19US060967; MN; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 50 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Sep-2019	02-Oct-2019*	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event on a 50 pound male canine, of further unknown signalment. 1 Sep 2019*: The pet owner applied an unknown amount of FRONTLINE PLUS DOG (unsubstantiated), to his dog, in an unknown location. Oct 2019*: The pet owner found 2 engorged ticks on his dog on an unknown date. The dog has been on FRONTLINE PLUS DOG for an unknown amount of time. He has access to 5 acres of woods. The pet owner cannot remember if he applied the FRONTLINE PLUS for Oct 2019. He has been using FRONTLINE PLUS DOG for an unknown length of time on the first of each month. This is the extent of

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ED_005739D_00014391-00328

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											information. No further medical information expected.
14-Oct-2019	UAE; 19US060973; MI; U.S.A	**Species:** Feline **Breed:** Feline various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 8 - 10 lbs	10	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Aug-2019*	14-Oct-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for Blackie and Tiger , 2 felines, 4-6 year old*, 8-10 pounds*, with remaining signalment unknown. Unknown date: The cats began receiving FRONTLINE PLUS CATS (lot unknown, package unavailable) monthly seasonally. The product was applied directly on the skin between the shoulder blades. 1 Aug 2019*: The pet owner applied the product to both cats. No ticks were seen prior to product application. 27 Sep 2019: The pet owner noticed one tick on both cats. 28 Sep 2018: The most recent date of application. 14 Oct 2019: The owner is still noticing a small amount of alive ticks on both cats. The cats a mostly outdoors, and do have access to areas with trees and brush. No treatments have been provided at home. The cats' current conditions are ongoing. There a total of 2 canines and 10 felines in the household. The remaining cats are treated with FRONTLINE PLUS, and have no fleas or ticks. The dogs are treated with Bravecto, and have no fleas or ticks. No further medical information expected.
14-Oct-2019	UAE; 19US060991; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2008*	14-Oct-2008*	13 Day(s)	D-A	Suspected Adverse Event: On 14 Oct 2019, the owner reported the following event for a canine of unknown signalment. Unknown: The pet began received FRONTLINE PLUS DOG (product unsubstantiated). 2008*: The pet passed away on an unknown date. Owner stated the pet passed away a few years ago. Death mentioned in relation to an inquiry about the expiration date for the product. No further medical information expected.
14-Oct-2019	UAE; 19US061028; KS; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 21 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	26-Sep-2019	13-Oct-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for Sophie, an 8 year old, 21 pound, spayed female, Maltese and Poodle Mix. Unknown date: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (T60614AL) monthly seasonally. The product was applied directly on the skin between the shoulder blades. 26 Sep 2019: The most recent date of application. 13 Oct 2019: The owner is still noticing a moderate amount of fleas. The dog has access to a fenced in yard, with trees and brush on the property. The owner did bathe the pet in a human shampoo. The dog's current condition is ongoing. There is one other dog in the household, who is also on FRONTLINE PLUS, with no reports or fleas. No further medical information expected.
14-Oct-2019	UAE; 19US061029; MO; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 30 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	14-Oct-2019	14-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019 the owner reported the following event for Lucy a 5 year old*, 30 pound*, spayed female, Shih Tzu. 15 Sep 2019*: The pet was exposed to a cat with a large amount of fleas on a family vacation. 13 Oct 2019: The owner noticed an unknown amount of fleas on the pet and applied one vial of FRONTLINE PLUS DOG 23-44 LBS (S61701AL) topically between the shoulder blades. 14 Oct 2019: The owner continues to notice fleas on the pet.

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ED_005739D_00014391-00329

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						Cutaneous **Was the product used ok?:** Yes					The pet has used FRONTLINE PLUS on unknown dates, the owner could not recall. The pet has access to a grass yard that backs up to woods. There is urban wildlife present in the yard. The pet is bathed with an unknown prescription pet shampoo every other week. The pet previously used FRONTLINE GOLD and had a reaction to the product, see case 19US046770. The pet has a history of environmental allergies and has had reactions to medications in the past. No further medical information expected.
14-Oct-2019	UAE; 19US061034; -; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 22 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Adam's flea and Tick shampoo; unknown herbal flea spray; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Oct-2019	11-Oct-2019	6 Day(s)	D-C	Suspected Adverse Event and Suspected Lack of Efficacy Claim : On 14 Oct 2019 a pet owner reported the following event for a 22 pound, 8 year old, 22 pound, female spayed Domestic Mediumhair. 4 Oct 2019: Owner saw a large amount of flea dirt on the cat and she was scratching. Owner bathed cat is Adam's Flea and Tick shampoo. 5 Oct 2019: Owner applied FRONTLINE PLUS CATS (S41305AW) to the skin between the animal's shoulder blades for the first time. 11 Oct 2019: Cat is still scratching and owner is seeing more flea dirt on the cat so she applied an unknown herbal flea spray to the cat and to the home. 12 Oct 2019: Owner applied more herbal flea spray the cat. 13 Oct 2019: Cat's itching increased greatly and her skin is twitching often. Owner feels this is from fleas even though she has seen no fleas on the animal. There cat lives indoors only. The owner has seen no fleas in the home. There are no other animals in the home. The cat has never had fleas and owner has never used a flea product on her. No further medical information expected.
14-Oct-2019	UAE; 19US061037; PA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 15 lbs	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Aug-2019	29-Aug-2019*	1 Day(s)	D-C	Suspected Adverse Event: On 14 Oct 2019, the owner reported the following event for Joey, a 15 pound, neutered male Domestic Shorthair. *28 Aug 2019: One vial of FRONTLINE PLUS CATS (S40601AX) was applied to the skin between the shoulder blades. *Unknown date: The cat developed a bald spot at the site of application. The hair is starting to grow back and is thin at the application site and the owner is using neosporin as treatment. The cat is treated with FL monthly year round and has not had any previous issues . There are two other treated cats in the home who hasn't had any symptoms. No further information available.
14-Oct-2019	UAE; 19US061055; NJ; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 16 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	08-Aug-2019	09-Sep-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 14 Oct 2019 a pet owner reported the following event for a 16 pound, 11 year old, spayed female crossbred dog. Aug 8 2019 and 9 Sep 2019: Owner applied FRONTLINE PLUS DOG S (S60322A) to the skin between the animal's shoulder blades. Sep 2019*: Dog began scratching, but owner has seen no fleas on the dog. Owner cannot clarify if the dog began scratching before or after the 9 Sep 2019 dose. The owner has not taken the dog to the clinic, but did talk to the clinic staff who told her if no fleas were seen she could give the dog Diphenhydramine, which owner has not done though the dog continued to scratch. Owner has not seen any fleas on the dog or in the home to date and has not treated the home. Prior to Aug 8 2019 the owner has used USA approved product on the dog monthly for years without issues. No further medical information is

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ED_005739D_00014391-00330

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											expected.
14-Oct-2019	UAE; 19US061059; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 65 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Aug-2019	14-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for a 65 pound canine of further unknown signalment. 12 Aug 2019, 12 Sep 2019, and 12 Oct 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) topically between the shoulder blades. 14 Sep 2019* to 14 Oct 2019: The owner continues to see 5 fleas on the dog daily. There is one other dog in the home, reference case 19US061074. The dog is indoor and goes outside to use the bathroom. There are no strays or wildlife in the area. The dog has not been bathed. There is carpet and hardwood in the home. The owner vacuums daily. The owner has not seen fleas in the home. No further medical information expected.
14-Oct-2019	UAE; 19US061063; MI; U.S.A	**Species:** Canine **Breed:** Cavalier King Charles **Sex:** F **Sex qualifier:** Unknown **Age:** 13.50 Year(s) **Weight:** 20 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2006*	07-Sep-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for Spec, a 13.5 years old, 20 pound, female Cavalier King Charles. 2006*: The pet began receiving FRONTLINE PLUS DOG 5-22 LBS (Lot unknown) (package unavailable), applied 1 vial topically between the shoulder blades monthly. 1 Sep 2019: Owner applied the monthly dose. 7 Sep 2019*: The owner noticed a moderate amount of fleas on the pet. 10 Sep 2019*: Owner bathed pet in Dawn dish soap. 20 Sep 2019*: Owner gave another bath with an unknown shampoo. 1 Oct 2019: Owner applied monthly dose. 7 Oct 2019*: Pet was groomed with a dog shampoo. 14 Oct 2019: Owner is still seeing fleas. The owner has not been noticing fleas off of the pet inside the home. There a total of 1 canine in the household. The yard is fenced with bushes. No further medical information expected.
14-Oct-2019	UAE; 19US061066; NY; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Oct-2019	14-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019 the owner called in the following report for Roly, a 11 year old*, 8 pound*, neutered male, Chihuahua. 25 Sep 2019*: The owner took the pet to a family members home and noticed the pet was itchy. 7 Oct 2019*: The pet continues to be itchy. The owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS (S61902AL) topically between the shoulder blades for the first time. 14 Oct 2019: The owner noticed an unknown amount of fleas on the pet. The dog is indoor only and has no access outside. There are no other pets in the home. It is unknown if fleas were seen prior to the application of FRONTLINE. The pet is in good health and has no history of reactions. The pet is bathed on unknown date with an unknown shampoo. No further medical information expected.
14-Oct-2019	UAE; 19US061074; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	12-Oct-2019	14-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for a canine of further unknown signalment. 12 Aug 2019, 12 Sep 2019, and 12 Oct 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 23-44

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ED_005739D_00014391-00331

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		Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					LBS (lot unknown, package unavailable) topically between the shoulder blades. It is unknown if fleas were seen at time of administration nor if this was the first dose received. 14 Sep 2019* to 14 Oct 2019: The owner continues to see 5 fleas on the dog daily. There is one other dog in the home, reference case 19US061059. The dog is indoor and goes outside to use the bathroom. There are no strays or wildlife in the area. The dog has not been bathed. There is carpet and hardwood in the home. The owner vacuums daily. The owner has not seen fleas in the home. No further medical information expected.
14-Oct-2019	UAE; 19US061082; NC; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 70 - 80 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	06-Sep-2019	14-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the owner reported the following event for 2 canines weighing 70-80 pounds (all other signalments unknown). 6 Sept 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) was applied between the shoulder blades. 14 Sept 2019: The owner started to notice fleas on the dogs for the first time. 15 Sept 2019: The owner applied another vial. The issue continued. 6 Oct 2019: Another vial was applied. 14 Oct 2019: The flea issue is still ongoing. Fleas have been noted in the home. The dogs environment is unknown. The dogs have received the product year round for the past few years (2016*) with no issue. No further medical information is expected.
14-Oct-2019	UAE; 19US061087; CA; U.S.A	**Species:** Canine **Breed:** Pointer (German Short-Haired) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 60 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Aug-2019*	14-Oct-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for Merlin, a 10 year old, 60 pound, neutered male, German Shorthaired Pointer and Ibizan Hound Mix. 5 Aug 2019*: The dog began receiving FRONTLINE PLUS DOG 45-88 LBS (S61501AR) monthly. The product was applied directly on the skin between the shoulder blades. 24 Aug 2019: The pet owner noticed a small amount of fleas. The pet also began scratching. The dog has access to a fenced in yard, with trees and brush on the property. The dog also goes on leash walks and to the dog park. 5 Sep 2019*: The pet owner applied a dose of FRONTLINE PLUS. 5 Oct 2019: The most recent date of application. 14 Oct 2019*: The dog has not presented to the veterinary clinic. Treatments have been initiated with an unknown dose of NEXGARD. The dog's current condition is ongoing. This is the only pet in the household. No further medical information expected.
14-Oct-2019	UAE; 19US061088; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used**	01-Jan-2019*	01-Jan-2019*	0 Day(s)	D-A	Suspected Adverse Event: On 14 Oct 2019, the pet owner reported the following event for a canine of unknown signalment. 2019*: The pet owner applied a dose of FRONTLINE PLUS (unsubstantiated) (lot unknown, package unavailable). Following on an unknown date, the dog passed away from unknown causes. It is unknown if the dog has received the FRONTLINE prior. Event mentioned in passing when pet owner inquired about expiration date for FRONTLINE PLUS. No further medical information expected.

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ED_005739D_00014391-00332

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					
14-Oct-2019	UAE; 19US061097; CA; U.S.A	**Species:** Canine **Breed:** Irish Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 32.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Oct-2019*	04-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 14 Oct 2019, the pet owner reported the following event, for Augie, a 32.0 pound, 11 year old, neutered male Irish Terrier. 4 Oct 2019*: The pet owner applied one dose of FRONTLINE PLUS DOG 23-44 LBS (lot unknown, reporter not queried), in one spot, between the shoulder blades to the dog. Immediately after application the dog shakes off some of the product as if he had gotten wet. The pet owner has applied FRONTLINE PLUS DOG 23-44 LBS previously, with the dog shaking the product off on unknown dates. This is the extent of information, as the pet owner was calling to ask about re-dosing since the dog shakes the product off. The dog has another case regarding (See Case 19US055565). No further medical information expected.
14-Oct-2019	UAE; 19US061100; OK; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	02-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for 4 dogs, with unknown signalment. May 2019*: The dogs received one dose of FRONTLINE PLUS DOG 45-88 LBS (S61810AX). The product was applied directly on the skin between the shoulder blades. 25 Sep 2019*: The pet owner reports seeing a severe amount of fleas. 1 Oct 2019: The most recent date of application. 2 Oct 2019: The owner is still noticing fleas. The dogs have access to a large fenced in yard. No treatments have been provided at home. The dogs' current conditions are ongoing. There a total of six canines and two felines in the household, who are also on FRONTLINE PLUS, and the owner reports fleas on them (See Cases 19US061113 and 19US061114). No further medical information expected.
14-Oct-2019	UAE; 19US061113; OK; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-May-2019*	02-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for 2 dogs, with unknown signalment. May 2019*: The dogs received one dose of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable). The product was applied directly on the skin between the shoulder blades. 25 Sep 2019*: The pet owner reports seeing a severe amount of fleas. 1 Oct 2019: The most recent date of application. 2 Oct 2019: The owner is still noticing fleas. The dogs have access to a large fenced in yard. No treatments have been provided at home. The dogs' current conditions are ongoing. There a total of six canines and two felines in the household, who are also on FRONTLINE PLUS, and the owner reports fleas on them (See Cases 19US061100 and 19US061114). No further medical information expected.
14-Oct-2019	UAE; 19US061114; OK; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical /	01-Oct-2019	02-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for 2 cats, with unknown signalment. May 2019*: The cats received one dose of FRONTLINE PLUS CATS (lot unknown, package unavailable). The product was applied directly on the skin between the shoulder blades. 25 Sep 2019*: The pet owner reports seeing a severe amount of fleas. 1 Oct 2019: The most recent date of application. 2 Oct 2019: The owner is still noticing fleas. The cats are outdoor.

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ED_005739D_00014391-00333

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** Yes					No treatments have been provided at home. The cats' current conditions are ongoing. There are a total of six canines and two felines in the household, who are also on FRONTLINE PLUS, and the owner reports fleas on them (See Cases 19US061100 and 19US061113). No further medical information expected.
14-Oct-2019	UAE; 19US061118; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jan-2019*	02-Jan-2019*	1 Day(s)	D-C	Suspected Adverse Event: On 14 Oct 2019, the owner reported the following event for two unknown felines (all signalments unknown). Unknown date: Owner applied FRONTLINE PLUS CATS (product unsubstantiated) (lot unknown, reporter refused) topically between the shoulder blades, by the owner. Unknown date: An unknown amount of time later, the cats had burns at the application site and scabs all over their heads. It is unknown if the cats were seen by the veterinarian or given any treatment. The cats' current status is unknown. No further information is known as the owner refused to complete the report. No further medical information expected.
14-Oct-2019	UAE; 19US061139; IL; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 17.00 Year(s) **Weight:** 8.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	16-Sep-2019*	17-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for Moe, a 17.0 year old, 8.0 pound, neutered male canine. 16 Sep 2019*: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S61006AL), in an unknown location to the dog. Sep 2019*: The dog stayed at a dog sitter's home for an unknown duration. The pet owner noticed flea dirt and fleas an unknown time after the dog returned home. 12 Oct 2019*: The pet owner applied the most recent dose. The pet owner is currently still seeing an unknown amount of fleas on the dog. The dog goes outside in grass for potty breaks. The pet owner previously used FRONTLINE PLUS DOG 5-22 LBS, but it is unknown when. There are two cats in the home that have been treated with FRONTLINE PLUS CATS, and the pet owner does not see fleas on the cats. No further medical information expected.
14-Oct-2019	UAE; 19US061145; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Oct-2019	14-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 14 Oct 2019, the pet owner reported the following event for a 4 month old female feline. 14 Oct 2019: The pet owner applied a dose of FRONTLINE PLUS CATS (lot unknown, lot not queried) for the first time. Shortly after applying, the cat licked the application site and she was walking around slower than usual and flicking her head a small amount. The cat's status was the same at the time of the phone call. No further medical information expected.
14-Oct-2019	UAE; 19US061160; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products**	2019*	12-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 12 Oct 2019, the pet owner e-mailed and reported the following for felines of unknown signalment. Unknown date: Pet owner applied FRONTLINE PLUS CATS (unsubstantiated) (lot unknown, package unavailable). An unknown volume per animal via an unknown route at an unknown

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ED_005739D_00014391-00334

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - **Weight:** Unknown				**used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					location. Unknown date: Pet owner seeing fleas on the cats. It is unknown if they presented to a veterinary clinic. It is unknown if any treatments have been administered. Their current condition is unknown. It is unknown what environment the felines frequent. It is unknown if the owner bathes the felines. It is unknown if there are any other pets in the household. This is the extent of information known as this is only information given in the email. No further medical information expected.
10-Oct-2019	UAE; 19US061167; MO; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	08-Jul-2019*	10-Jul-2019*	2 Day(s)	D-C	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 10 Oct 2019, a pet owner reported the following event for Lizzy, an approximately 7 year old, 8 pound, spayed female Domestic Longhair. 2018*: The cat began receiving monthly applications of FRONTLINE PLUS CATS (S41004AW) topically between the shoulder blades in one spot during the summer months. 8 Jun 2019*: The cat started receiving monthly applications of FRONTLINE PLUS CATS for the first time this year. The owner is unsure if the cat had fleas prior to the application. 8 Jul 2019*: The cat received 1 application. 10 Jul 2019*: The cat was lethargic and not wanting to eat or drink. Her hind legs were not working very well, she would fall over when trying to stand. She presented to the veterinary clinic and radiographs were taken to rule out being hit by a car and were unremarkable. Bloodwork revealed that the cat was anemic and per the pet owner the veterinarian stated that it was due to fleas. However, the pet owner was unsure if she had seen fleas on the cat. The cat received an unknown flea pill. 12 Jul 2019*: The cat was bathed in Dawn detergent. 15 Jul 2019*: The cat was recovered. No further medical information expected.
14-Oct-2019	UAE; 19US061185; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2018*	10-Oct-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for Apache, a 6 year old, neutered male, feline of further unknown signalment. Oct 2018*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (S40601AX) topically between the shoulder blades monthly. 01 Oct 2019: The most recent dose was applied. 10 Oct 2019: The cat presented to the veterinarian and the veterinarian saw 8 fleas on the cat. The cat was treated with an unknown treatment. The cat recovered. The cat is indoor and outdoor. There are 5 other cats in the home that do not have fleas on them and are not treated with anything. There are no strays or wildlife in the environment. There is carpet, hardwood, tile, and linoleum in the home. The owner sprayed the home. The owner is not seeing any fleas in the home. No further medical information expected.
14-Oct-2019	UAE; 19US061199; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	01-Oct-2018*	01-Oct-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the pet owner reported the following event for a dog with unknown signalment. 2018*: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable) monthly with unknown purchase history. Product application details are unknown. Fleas were seen prior to product application. The most recent date of application is unknown, but the pet owner claims to apply it every month.

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ED_005739D_00014391-00335

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** Unknown to Company					1 Oct 2019*: The dog went hiking with the pet owner. The pet owner found a single tick and chewing lice on the dog after the hike. The dog has not presented to the veterinary clinic. No treatments have been provided at home. The dog's current condition is ongoing. It is unknown if there are any other animals in the household. No further medical information expected.
14-Oct-2019	UAE; 19US061206; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Sep-2018*	28-Sep-2019*	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Oct 2019, the owner reported the following event for 3 cats (signalment unknown) *28 Sep 2019: The cat had fleas for about a month and a half and one vial of FRONTLINE PLUS CATS (S40601AX) was applied to the skin between the shoulder blades to each cat. The cats are strictly indoors and continued to pick up fleas. The cats are treated monthly year round and the owner is not being bit inside the home. There are 7 outside cats that are not treated. No further information available.
15-Oct-2019	UAE; 19US061222; CT; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 12.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Apr-2019*	30-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the pet owner reported the following event for Izzy, a 13 year old, 12.0 pound, female feline, of further unknown signalment. 1 Apr 2019*: The pet owner applied an unknown amount of FRONTLINE PLUS CATS (lot unknown, package unavailable), to an unknown location, to the cat. 30 Apr 2019*: The pet owner notices 1 to 2 fleas on the cat, as well as flea dirt. The pet owner has not seen any fleas in the home. The cat goes outside and likes to go under different porches of the neighbors . There are no other pets in the home and the cat is in good health. The cat is not taking any other medications. The pet owner has used FRONTLINE PLUS CATS previously, monthly, except for the months of January and February, since a year ago on an unknown date. No further medical information available.
15-Oct-2019	UAE; 19US061223; IN; U.S.A	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** X **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 19 - 21 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	08-Sep-2019*	01-Oct-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the pet owner reported the following event for Addie and Joe , 4-5 years*, 19-21 pound, male and female, neutered, Jack Russell Terriers. Unknown date: The dogs began receiving FRONTLINE PLUS DOG 5-22 LBS (S61017AL) every 14 days year round. The product was applied directly on the skin between the shoulder blades. 8 Sep 2019* and 22 Sep 2019*: The pet owner applied the product. 1 Oct 2019*: The pet owner noticed an unknown amount of fleas on both pets. The dogs have access to a fenced in yard, with trees and brush on the property. 10 Oct 2019*: The most recent date of application. The pet owner bathed the dogs in a Hartz flea shampoo. The dogs' current conditions are ongoing. These are the only in the household. No further medical information expected.
15-Oct-2019	UAE; 19US061249;	**Species:** Canine **Breed:** Pit Bull	1	1	0	**Product used:** FIPRONIL	09-Jul-2019*	09-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019 the owner reported the following event for Mabel, a 7 year old, 53 pound*,

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ED_005739D_00014391-00336

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	LA; U.S.A	**Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 53 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					spayed female, Pit Bull. 9 Mar 2019* through 9 Jul 2019*: The owner applies one vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) topically between the shoulder blades seasonally, monthly. No fleas were seen prior to the start of the season. 9 Aug 2019: The owner had family staying on the property with untreated dogs. The owner noticed an unknown amount of fleas on the pet. The untreated dogs did not have access to the home, but interacted with the owners pet. The owner applied FRONTLINE PLUS to her pet. 9 Sep 2019: The owner continues to see fleas on the pet and applies the product. 9 Oct 2019: the owner continues to see fleas on the pet and applies the product. The pet has access outside to a two acre rural property with urban wildlife and farm animals present. The pet is bathed infrequently on unknown dates with an unknown pet shampoo. The owner is seeing an unknown amount of fleas in the home only when the pet is around. as per the pet owner, the amount of fleas has decreased since the untreated dogs left her property. The pet has seasonal allergies and has no history of reactions. No further medical information expected.
15-Oct-2019	UAE; 19US061271; OH; U.S.A	**Species:** Feline **Breed:** Turkish Angora **Sex:** F **Sex qualifier:** Neutered **Age:** 11.50 Year(s) **Weight:** 14 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	16-Sep-2019	01-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the pet owner reported the following event for Bittle, an 11.5 years old, 14 pound, female spayed Turkish Angora mix. April 2008: The pet began receiving FRONTLINE PLUS CAT (Lot unknown) (package unavailable), applied 1 vial topically between the shoulder blades seasonally from April to November. 16 Sep 2019: Owner applied monthly dose, FRONTLINE PLUS CAT (S40606AW). 1 Oct 2019*: Owner noticed the pet scratching more and took her to a groomer. The groomer found a moderate amount of fleas on the pet. 7 Oct 2019: Owner applied the monthly dose. 14 Oct 2019: The owner was still seeing fleas. Owner applied Revolution. 15 Oct 2019: The owner is no longer seeing fleas. The owner has not been noticing fleas off of the pet inside the home. The yard is wooded. The pet is indoor/outdoor. There are no other pets in the home. No further medical information expected. UPDATE 31 DEC 2019: Corrected owner's first name spelling on contact screen.
15-Oct-2019	UAE; 19US061278; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown	01-Oct-2019*	15-Oct-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019 an animal owner reported the following event in her canine. All other signalment unknown. 01 Oct 2019*: The feline was administered FRONTLINE PLUS CATS (lot expiration unknown. Package unavailable). There were several fleas on feline and in home at time of administration. It is unknown if this was the first dose administered. 15 Oct 2019: The animal owner is still seeing fleas, but there are less then at time of FRONTLINE PLUS administration. There are no other pets in the household. The feline is indoor only. The animal owner is vacuuming, washing bedding, and combing cat with flea comb. Intent of call was not to report. Caller declined further case details. No further information provided nor expected.

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Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					
15-Oct-2019	UAE; 19US061285; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	23-Sep-2019	08-Oct-2019*	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the pet owner reported the following event for 2 cats of unknown signalments. 23 Oct 2018*: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (lot unknown/ package unavailable) to the skin between the shoulder blades monthly for the first time. 23 Sep 2019: A dose was applied. 08 Oct 2019*: The owner noticed the pets scratching and found an unknown quantity of live fleas. 15 Oct 2019: The owner reports still seeing an unknown quantity of live fleas on the cats. There are no other pets in the home. The cats are indoors only. The pets are not bathed. The owner was unwilling to provide additional information. No further medical information expected.
15-Oct-2019	UAE; 19US061319; WA; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** - **Age:** 6.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Jul-2019	15-Oct-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 15 Oct 2019, a pet owner reported the following event for Katie, an 8 pound, 6 year old, spayed female, Shih Tzu. Jun 2019: The pet owner noticed that the dog had more than 20 fleas on her. 23 Jul 2019: The pet owner purchased and applied for the first time ever 1 dose of FRONTLINE PLUS DOG 5-22 LBS (S61902AL), topically between the shoulder blades. The dog is indoor/outdoor, she has access to a fenced in backyard with grass, bushes and 1 tree. The dog spends the majority of her time indoors. There are 2 cats as well in the hone but the owner is not having flea issues with them. The cats are on FRONTLINE PLUS CATS (unknown lot number, package unavailable). 23 Aug 2019 and 23 Sep 2019: The owner applied 1 dose of FRONTLINE to the dog. 15 Oct 2019: The pet owner is still seeing a large amount of fleas on the dog. The issue is ongoing. No further medical information expected.
15-Oct-2019	UAE; 19US061320; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	20-Sep-2019	08-Oct-2019*	18 Day(s)	D-D	Suspected Adverse Event: On 15 Oct 2019, the pet owner reported the following event for a male feline, of further unknown signalment. 20 Sept 2019: The pet owner applied an unknown amount of FRONTLINE PLUS CATS (lot unknown, reporter not queried), to an unknown location on the cat. 8 Oct 2019*: The pet owner noticed that the cat was scratching. The pet owner did not see fleas. The pet owner currently does not see fleas on the cat, but still notes that the cat is scratching. It is unknown if this is the first time the cat has received FRONTLINE PLUS CATS. There are 2 other cats in the home that have received FRONTLINE PLUS CATS with no issues reported. This is the extent of information, as the pet owner called to inquire about re-dosing. No further medical information expected.
15-Oct-2019	UAE; 19US061323; OH; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other	02-Aug-2019	30-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the pet owner reported the following event for Brownie, a 11 year old, 9 pound, spayed female, Domestic Shorthair. 2 Aug 2019: The cat began receiving FRONTLINE PLUS CATS (lot unknown, package unavailable) monthly. The product was applied directly on the skin between the shoulder blades. 30 Aug 2019: The pet owner noticed flea dirt on the cat. The cat

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ED_005739D_00014391-00338

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 11.00 Year(s) **Weight:** 9 lbs				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					has access to an open area, with trees and brush on the property, and access to under decks and crawl spaces. 2 Sep 2019 and 2 Oct 2019: The most recent dates of application. 15 Oct 2019: The owner is still noticing flea dirt. No treatments have been provided at home. The cat's current condition is ongoing. This is the only pet in the household. No further medical information expected.
15-Oct-2019	UAE; 19US061329; MI; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Month(s) **Weight:** 65 lbs	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	04-Oct-2019*	14-Oct-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim:On 15 Oct 2019, the owner reported the following event for Rusty ,male neutered, 11 month old, 65 pound , Labrador Retriever. 4 Oct 2019: One vial of the FRONTLINE PLUS DOG 89-132 LBS (S60105AR) was applied topically in between the shoulder blades by the owner. The owner purchased a 3 pack at an unknown date. 14 Oct 2019: The vet clinic noticed unknown amount of fleas still on the dog while under anesthesia for a neuter. The dog is indoor mostly and has access to a fenced in yard. Fleas are not seen within the home and it is unknown if wildlife is seen within the area. The owner also has a 2 other dogs treated with FRONTLINE and not having any issues with fleas. Fleas were not seen on the pet prior to use.The is the 4 th dose for the dog. No further medical information is expected.
15-Oct-2019	UAE; 19US061330; OH; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	7	7	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Apr-2019*	20-May-2019*	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the pet owner reported the following event for 7 cats of unknown signalment. Apr 2019*: The pet owner started applying monthly doses of FRONTLINE PLUS CATS (lot unknown, package unavailable) to each of the cats. May 2019*: The pet owner started finding fleas on the cats. 15 Oct 2019: The pet owner is still finding fleas on the cats. The cats stay inside. There is a dog in the home who is on Bravecto and does not have fleas. There are fleas in the home and the home was treated. One of the cats was bathed. The cats were treated with Revolution. Case was reported with case 19US061336. No further medical information expected.
15-Oct-2019	UAE; 19US061334; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	13-Oct-2019*	14-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the pet owner reported the following event for a canine of unknown signalment. 1 Oct 2019*: Ticks were noticed on the animal. 13 Oct 2019*: The patient got their dose of FRONTLINE PLUS DOG (Unsubstantiated)(lot unknown, reporter refused). It is unknown if the animal has had FRONTLINE before, and it is unknown where it was applied on the animal. 14 Oct 2019: The owner noticed some ticks were still attached to the animal. It is unknown if the pet goes outside, it unknown if the pet gets bathed, and it is unknown if the owner is seeing ticks in the house or on herself. The owner did remove one tick, but left the others. The ticks were not identified. The patient's current condition is ongoing. It is unknown if there are other animals in the household. Reporter refused further inquiry, they were primarily calling to see how long it takes for the ticks to die after FRONTLINE. No further medical information expected.
15-Oct-2019	UAE; 19US061336;	**Species:** Feline **Breed:** Feline	1	1	1	**Product used:** FIPRONIL	20-Sep-2019*	07-Oct-2019*	17 Day(s)	D-A	Suspected Adverse Event and Suspected Lack of Efficacy Claim : On 15 Oct 2019, the pet owner reported the following event for a

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ED_005739D_00014391-00339

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	OH; U.S.A	(unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					feline of unknown signalment. 20 Sept 2019*: The pet owner applied a dose of FRONTLINE PLUS CATS (lot unknown, package unavailable). 7 Oct 2019*: The pet owner found the cat deceased covered in fleas in the basement where the cats stayed. The cat has been receiving FRONTLINE for an unknown number of years. Case was reported with case 19US061330. Caller declined to report and no necropsy was performed. No further medical information expected.
15-Oct-2019	UAE; 19US061352; WI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2018*	01-Jan-2018*	N/A	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the clinic reported the following event for a canine of further unknown signalment. 2018*: The pet owner applied an unknown amount of FRONTLINE PLUS DOG (unsubstantiated) (lot unknown, reporter refused), to an unknown location on the dog. Fleas were noted on the dog and in the house. Unknown date 2018*: The home was treated by Terminix. 1 Oct 2019*: The most recent dose was applied to the dog. Fleas are still being noticed in the home and on the dog. The dog has used FRONTLINE PLUS DOG monthly since an unknown amount of time. This is the extent of information, as the clinic disconnected. No further medical information expected.
15-Oct-2019	UAE; 19US061383; -; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 17.00 Month(s) **Weight:** 93 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)	15-Oct-2019	15-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 15 Oct 2019, the pet owner reported the following event for Perry, 93 pounds, 17 month (1 May 2018), neutered male, mixed breed. 15 Jul 2019*: The owner began applying the contents of 1 vial FRONTLINE PLUS DOG 45-88 LBS (S63106AX) topically in an unknown location monthly for the first time. 15 Oct 2019: The owner applied a dose. Within 5 minutes of application, the dog began to run around the house as if in pain. The owner used a paper towel to remove some product, then applied a waterless human shampoo to remove any remaining. The pet calmed down and is now recovered. The owner reported this incident to her vet and switching products. No further medical information available.
15-Oct-2019	UAE; 19US061385; MI; U.S.A	**Species:** Feline **Breed:** Feline various breeds **Sex:** X **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 7 - 15 lbs	4	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Sep-2019	15-Oct-2019	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019 the owner reported the following event for 4 various breed felines, 7 to 15 pound*, 12 to 14 years*, mixed neutered male and spayed females. 20 Jan 2017 through 20 Sep 2019: The owner applies one vial of FRONTLINE PLUS CATS (S41006AW) topically between the shoulder blades year round, monthly. Fleas were not seen on pets prior to the first application. 15 Oct 2019: The owner brought 2 of the pets to the veterinarian for a rabies vaccine and the technician at the clinic informed the owner that the two felines had lots of flea dirt on them along with two fleas seen on each cat. There are two felines that are house pets with access outside where there is urban wildlife present. The other two felines who were brought to the veterinarian and had two fleas seen on them are barn cats and live outside with no access to the home. The owner has not seen fleas on the two house cats, but is convinced if

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ED_005739D_00014391-00340

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											the two barn cats have fleas these cats also have fleas. There are no other pets in the home. There are no fleas seen in the home. The pets are in good condition and have no history of reactions. No further medical information expected.
15-Oct-2019	UAE; 19US061392; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 80 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Overdose)	01-Jan-2019*	02-Jan-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the owner reported the following event for an 80 pound dog (all other signalments unknown). Unknown date: Started on FRONTLINE PLUS DOG 89-132 LBS (lot unknown, reporter refused) it is unknown if this was the first dose or if the dog had fleas prior to the application. On an unknown date after the application, the owner saw fleas on the dog. The owner mentioned treating the yard. There are 2 other dogs also being treated with FRONTLINE (see case 19US061433). The owner refused to complete the report. No further medical information expected.
15-Oct-2019	UAE; 19US061399; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	19-Sep-2019	14-Oct-2019	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019 a pet owner reported the following event for a canine of unknown signalment. 19 Sep 2019: Owner applied FRONLTINE PLUS DOG (unsubstantiated) (lot unknown) topically in an unknown location. 14 Oct 2019: Owner found a live and engorged tick on the dog. It is unknown if the owner removed the tick. The owner became upset during the call and ended the call, so no further details are known. No further information at this time.
15-Oct-2019	UAE; 19US061417; NY; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 10.000 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Oct-2019	15-Oct-2019	12 Day(s)	D-D	Suspected Lack of Efficacy Claim:On 15 Oct 2019, the owner reported the following event for Oscar, a 10-15* pound 5 year old, male neutered, Domestic Shorthair. 3 Oct 2019: One vial of the FRONTLINE PLUS CATS (S40404AW) was applied topically in between the shoulder blades by the owner. The owner purchased a 3 pack at an unknown date. 15 Oct 2019: The owner noticed 2 ticks engorged on the cat and 1 that had fallen off. The cat is indoor/outdoor. There are no visiting pets to the home, but the cat lives on a farm where wildlife is present. This is the first dose of FRONTLINE PLUS for the cat. No further medical information is expected. UPDATE 25 NOV 2019: Corrected VeDDRA code to LOE.
15-Oct-2019	UAE; 19US061421; IL; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 8 - 20 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	01-Oct-2019	14-Oct-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the pet owner reported the following event for 2 felines of unknown signalment, weighing 8 and 20 pounds. 1 Oct 2019: The pets began receiving FRONTLINE PLUS CAT (Lot unknown) (package unavailable), applied 1 vial per animal topically between the shoulder blades for the first time. No fleas noted at this time. 14 Oct 2019*: The owner noticed a small amount of fleas on the pet. The owner has not been noticing fleas off of the pet inside the home. The cats are indoor/outdoor. There a total of 4 felines in the

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ED_005739D_00014391-00341

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					household. The yard is fenced. The other 2 cats are outdoor only and have not been treated yet. The outdoor cats do have fleas. No further medical information expected.
02-Oct-2019	UAE; 19US061430; FL; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Mixed **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	04-Sep-2019	05-Sep-2019*	1 Day(s)	D-C	Suspected Adverse Event: On 2 Oct 2019, the pet owner reported the following event for 1 canine of unknown signalment. Oct 2016*: The pet began receiving monthly FRONTLINE PLUS DOG 23-44 LBS (Lot unknown) (package unavailable). Owner applied 1 vial per animal topically between the shoulder blades. The pet is treated year round. 4 Aug 2019: Owner applied the monthly dose, FRONTLINE PLUS DOG 23-44 LBS (S60713) from an 8 pack bought at Sams. 4 Sep 2019: Owner applied the monthly dose. Sep 2019*: The pet presented to the veterinarian for vomiting, lethargy and hives related to the flea bites (flea lack of efficacy reported in case 19US058881). The owner has been noticing fleas off of the pets inside the home . The yard is fenced. It is unknown what treatment was given to the pet and if the pet has recovered. There a total of 6 canines in the household. See case 19US058867 and 19US058881. No further medical information expected.
15-Oct-2019	UAE; 19US061431; WI; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 5.0 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	13-Sep-2019	15-Oct-2019	4 Week(s) 4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the pet owner reported the following event for Tig, a 3 to 4 year old, 5.0 pound, neutered male feline. 13 Sep 2019*: The pet owner applied one dose of FRONTLINE PLUS CATS (lot unknown, package unavailable), in one spot, between the shoulder blades to the cat. 15 Oct 2019: The pet owner saw 4 ticks on the cat that were attached and removed them from the cat. The cat goes outside and has access to woods that are near the home. There is 1 other cat and 2 other dogs in the home that received FRONTLINE PLUS. The cat has received FRONTLINE PLUS previously for approximately 2 years. No further medical information expected.
15-Oct-2019	UAE; 19US061437; RI; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 11 lbs	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	31-Aug-2019*	31-Aug-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 15 Oct 2019, the pet owner reported the following event for Mistoffeleef, 11 pounds, 11 year, neutered male, Domestic Shorthair. 31 Aug 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (lot unknown/ package unavailable) to the skin between the shoulder blades for the first time after noticing an unknown quantity of live fleas. The owner noticed the pet began scratching around his neck more. 07 Sep 2019*: The owner reported scabbing and fur loss around the application site. There are 2 other cats (19US057183) and 1 dog (19US056244) in the home currently being treated with FRONTLINE PLUS with lack of efficacy reports. The owner discontinued the use of the product for this cat. The owner reports planning on using Capstar in the future. No further medical information expected.
15-Oct-2019	UAE; 19US061452; FL; U.S.A	**Species:** Canine **Breed:** Basset Hound **Sex:** F **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	05-Sep-2019	01-Oct-2019*	26 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the pet owner reported the following event for Prissy, a neutered female, Basset Hound. 2009*: The dog began receiving 1 full vial of FRONTLINE PLUS DOG 45-88 LBS (S60104AR) between the shoulder blades monthly.

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ED_005739D_00014391-00342

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - **Weight:** Unknown				**used:** Oatmeal shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					05 Sep 2019: The most recent dose was given. 17 Sep 2019*: The dog was bathed with oatmeal shampoo. 01 Oct 2019* to 15 Oct 2019: The owner continues to see 6-8 fleas on the dog daily. There are no other pets in the home. The dog is indoor and goes outside to use the bathroom.The owner has not been bit by the fleas and is not seeing fleas in the home. There is carpet and hardwood in the home. There are no strays or wildlife in the environment. No further medical information expected.
15-Oct-2019	UAE; 19US061459; PA; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Neutered **Age:** 2.50 Year(s) **Weight:** 65.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Oct-2019	14-Oct-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the owner reported the following event for Luda, female neutered, 2.5 year old, 65 pound Pitbull and Hound Mix. 4 Oct 2019: One vial of the FRONTLINE PLUS DOG 45-88 LBS (S61810AX) was applied topically in between the shoulder blades by the owner. The owner purchased a 3 pack at an unknown date. 14 Oct 2019: The owner noticed a moderate amount of fleas still on the dog after using the product since June. The dog is indoor mostly with access to a fenced yard. Fleas are not seen within the home and wildlife is seen within the area. The owner also has a cat that is not treated but not having any issues with fleas. Fleas were not seen on the pet prior to use. The owner has used the product since Jun*and continues until the first snowfall .The owner did bathe the dog in a flea shampoo at an unknown frequency. No further medical information is expected.
15-Oct-2019	UAE; 19US061461; KS; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 5 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Sep-2019	09-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019 an animal owner reported the following event in Charlie, a 7 year old, 5 pound, male neutered Maltese. 09 Sep 2019: The canine was adminsitered FRONTLINE PLUS 5-22 LBS (562507RX) between the shoulder blades. 09 Oct 2019: The canine was administered 1 vial of FRONTLINE PLUS between the shoulder blades. There were fleas seen on the canine at time of administration. 15 Oct 2019: Flea dirt was seen on the canine. The canine has been receiving monthly doses of FRONTLINE PLUS since 2012* without issue. There is another Maltese in the household that is on FRONTLINE PLUS. No fleas seen on canine. No further information provided nor expected.
15-Oct-2019	UAE; 19US061472; -; U.S.A	**Species:** Canine **Breed:** Great Pyrenees **Sex:** U **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 90 - 100 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2019	21-Sep-2019*	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Oct 2019, the pet owner reported the following event for 3 dogs, 3-7 years, 90-100 pounds, mixed sex, Great Pyrenees, with remaining signalment unknown. 1 Apr 2018*: The dog began receiving FRONTLINE PLUS DOG 89-123 LBS (P62803AR) monthly. The product was applied directly on the skin between the shoulder blades. 1 Sep 2019: The product was applied. 21 Sep 2019*: The owner has noticed fleas and ticks on the dogs. The dogs are outdoor only, and have access to an open area, with trees and brush on the property, and access to crawling under decks and crawl spaces. No treatments have been provided at home. The dogs' current conditions are ongoing. 1 Oct 2019: The most recent date of application. 15 Oct 2019: The pet owner is still seeing fleas and ticks. There are an unknown number of cats also in the household, who are not treated with FRONTLINE, but have no reports of fleas/ticks. No further medical information expected.

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ED_005739D_00014391-00343

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
16-Oct-2019	UAE; 19US061482; ME; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 8 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Aug-2019*	16-Oct-2019	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019 the owner reported the following event for Blinks, a 4 year old*, 8 pound*, neutered male, Domestic Shorthair. 1 Oct 2018* through 1 Sep 2019*: The owner applied one vial of FRONTLINE PLUS CATS (S41004AW) topically between the shoulder blades monthly, year round. 1 Oct 2019*: The owner applied FRONTLINE PLUS to the pet. 16 Oct 2019: The owner found 4 engorged ticks on the pet. The species of the ticks are unknown. It is unknown if the owner removed the ticks. The pet has access outside to woods where urban wildlife is present. It is unknown if there are other pets in the home. The pet is bathed on unknown dates prior to application with an unknown shampoo. It is unknown if ticks have been seen on the pet prior. No further medical information expected.
16-Oct-2019	UAE; 19US061489; CA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 6 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jan-2018*	02-Jan-2018*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019 the owner reported the following event for Linx a 4 year old*, 6 pound*, neutered male, unknown feline. Unknown Date 2018*: The owner applied one vial of FRONTLINE PLUS CATS (J40704AW) topically between the shoulder blades. It is unknown if this is the first time. Unknown Date: The owner continued to see an unknown amount of fleas on the pet. It is unknown how often the product was used. The pet is indoor only and has no access outside. There are no other pets in the home. It is unknown if there were fleas seen prior to application of FRONTLINE PLUS. It is unknown how often the product was applied. No further medical information expected. Suspected
16-Oct-2019	UAE; 19US061491; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Oct-2019	11-Oct-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for Theodore , a feline of further unknown signalment. 2019*: Prior to FRONTLINE the cat was on Advantage II summer seasonally with no issues. 4 Oct 2019: The patient got their first dose of FRONTLINE PLUS CATS (lot unknown, reporter refused).It is unknown how many vials were purchased, and it is unknown as to how the owner applied it. 11 Oct 2019*: The owner noticed ticks on the cat. It is unknown if the ticks were identified. It is unknown how often the pet goes outside, it is unknown if the pet is bathed, it is unknown if the cat is having skin issues, and it is unknown if the owner is seeing ticks in the house or on herself. The patient's current condition is ongoing. There is a total of 2 felines in the household, and the other feline has a case for FRONTLINE as well. See case 19US061527. The reporter refused further inquiry as the owner was primarily calling for a refund on the product. No further medical information expected.
16-Oct-2019	UAE; 19US061505; TN; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	01-Oct-2019*	16-Oct-2019	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019 the pet owner reported the following event via mail for two canines of unknown signalment. Unknown Date: Started on FRONTLINE PLUS DOG 5-22 LBS (lot number unknown, package unavailable) (product unsubstantiated), unknown volume, route, or application site. It is unknown if fleas were seen prior to application.

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Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products **Route:** unknown **Was the product used ok?:** Unknown to Company					16 Oct 2019: The pet owner reported the product was ineffective. Currently, it is unknown if there are fleas on the canines or in the environment, or what outside areas they have access to. It is also unknown if there are any other pets in the household. No further medical information is expected.
16-Oct-2019	UAE; 19US061513; MA; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 15.00 Month(s) **Weight:** 13.2 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	23-Aug-2018	08-Oct-2019	1 Week(s)	D-C	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the veterinary technician reported the following event for Luna, a 15 month old (born 7 Jul 2018), 13.2 pound, spayed female, Yorkshire Terrier/Shih Tzu mixed breed canine. 23 Aug 2018: Started on monthly doses of FRONTLINE PLUS DOG 5-22 LBS (M63316AL) topically by the owner. 8 Oct 2019: The dog tested positive for Anaplasma via a 4DX test. The dog has not received any treatment. The owner has not seen any ticks on the dog. No further medical information expected.
16-Oct-2019	UAE; 19US061525; IL; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Oct-2019	14-Oct-2019*	12 Day(s)	D-D	Suspected Adverse Event: On 16 Oct 2019, the owner reported the following event for Bella, a 2 year old, 10 pound, female canine of unknown breed. 2 Sep 2019: The pet received FRONTLINE PLUS DOG 5-22 LBS (R624128AL), applied topically between the shoulder blades for the first time. 2 Oct 2019: Owner applied another dose. The owner noticed the pet itching and irritated on the underside of her neck, opposite the application site. 14 Oct 2019*: The owner continues to notice the irritation intermittently. The owner is unsure if the 2 Sep dose caused the same irritation. The pet has not presented to the veterinarian. The pet has no pertinent medical history and no history of drug reactions. No further medical information expected.
16-Oct-2019	UAE; 19US061527; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Oct-2019	11-Oct-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for Tip, a feline of further unknown signalment. 2019*: Prior to FRONTLINE the cat was on Advantage II summer seasonally with no issues. 4 Oct 2019: The patient got their first dose of FRONTLINE PLUS CATS (lot unknown, reporter refused).It is unknown how many vials were purchased, and it is unknown as to how the owner applied it. 11 Oct 2019*: The owner noticed fleas on the cat. It is unknown how often the pet goes outside, it is unknown if the pet is bathed, it is unknown if the cat is having skin issues, and it is unknown if the owner is seeing fleas in the house or on herself. The patient's current condition is ongoing. There is a total of 2 felines in the household, and the other feline has a case for FRONTLINE as well. See case 19US061491. The reporter refused further inquiry as the owner was primarily calling for a refund on the product. No further medical information expected.
16-Oct-2019	UAE;	**Species:** Feline	2	1	0	**Product used:**	01-Oct-2019*	16-Oct-2019	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner

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ED_005739D_00014391-00345

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19US061553; WI; U.S.A	**Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** Unknown				FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					reported the following event with 1 feline, neutered male, all other signalments unknown. 01 Oct 2017*: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (S40210AW) topically in an unknown location monthly for the first time. 01 Oct 2019*: The owner applied a dose. 02 Oct 2019*: The owner found live engorged deer ticks on the pet it is unknown if they were attached. The owner removed the ticks. 16 Oct 2019: The owner reports continuing to find ticks on the pet. There is 1 other adult cat treated with FRONTLINE PLUS in the home and 6 kittens. The adults are indoor/ outdoor. There is a forested area behind the home. Feral cats are frequently seen near the house. No further medical information expected.
16-Oct-2019	UAE; 19US061555; NC; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Sep-2019	10-Oct-2019*	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, an owner reported the following event in a male feline of unknown further signalment. 30 Sep 2019: The owner administered one FRONTLINE PLUS CATS (lot unknown, package unavailable) topically at the base of the skull for the eighth month in a row. No fleas were seen at the time of application. 10 Oct 2019*: The owner saw the cat scratching and flea dirt on him. An unknown amount of fleas were seen. 14 Oct 2019: The owner bathed the cat in dawn to kill the fleas. The cat is indoor-outdoor in an unknown environment. There are no other animals in the home. No further medical information expected.
16-Oct-2019	UAE; 19US061564; NY; U.S.A	**Species:** Feline **Breed:** Ragdoll **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL 9.8% / S-METHOPRENE 11.8% / PYRIPROXYFEN 0.25% TOPICAL SOLUTION; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Oct-2019	25-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019 the owner called in the following event for Fluff, a 6 year old*, 15 pound*, neutered male, Ragdoll crossbred feline. 18 Apr 2019* through 18 Jun 2019*: The owner applied one vial of FRONTLINE PLUS CATS (S4140AW) topically between the shoulder blades. No fleas were seen prior to application. 18 Jul 2019: The owner purchased FRONTLINE GOLD FOR CATS (PP26981) and applied one vial topically between the shoulder blades for the first time. 18 Aug 2019 through 16 Sep 2019: The owner applied FRONTLINE GOLD to the pet. 25 Sep 2019*: Owner noticed a few fleas on the pet. 12 Oct 2019:The owner noticed flea dirt on the pets chest. The owner applied FRONTLINE PLUS to the pet. 16 Oct 2019: The owner continued to notice an unknown amount of fleas on the pet. The pet has access outside to a wooded area. There are no other pets in the home. The pet is leash walked into town. No fleas are seen in the home. The pet is not bathed. No further medical information expected.
16-Oct-2019	UAE; 19US061571; MI; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 13 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical /	01-Jun-2019	01-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the owner reported the following event for a 13 pounds, neutered male, Domestic Shorthair (all other signalments unknown). 1 June 2019: The cat started on FRONTLINE PLUS on a monthly basis. It is unknown if fleas were seen at time of application. 1 Oct 2019: The most recent vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) was applied between the shoulder blades, by the pet owner. The cat had fleas. 15 Oct 2019: The cat present to clinic and another flea preventative was applied.

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						Cutaneous **Was the product used ok?:** Yes					The cat does not get bathed. The owner is noticing flea activity in the household. The cat is an indoor/outdoor cat. No further medical information is expected. UPDATE 01 Nov 2019: The contact information was updated. No further medical information is expected
16-Oct-2019	UAE; 19US061585; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 35 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Sep-2019*	19-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the owner reported the following event for 2 canines weighing about 35 pounds (all other signalments unknown). Unknown date: The owner started to notice fleas. 18 Sept 2019: One vial of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown, package unavailable) was applied between the shoulder blades. It is unknown if the dogs received the product before. 19 Sept 2019*: The owner continued to notice fleas. 16 Oct 2019: The current status is unknown. The dog's environment is unknown. No further medical information is expected.
16-Oct-2019	UAE; 19US061587; CA; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 5 - 22 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Jul-2019	22-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for 3 dogs, 5 to 22 pounds, all other signalments unknown. 21 Jan 2018*: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 5-22 LBS (T60214AL) to the skin between the shoulder blades of each dog monthly for the first time. 21 Jul 2019: A dose was applied. 22 Jul 2019*: The owner saw an unknown quantity of live fleas on all the dogs. 2 dogs had a heavier burden than 1. 21 Aug 2019: A dose was applied. 21 Sep 2019: A dose was applied. 16 Oct 2019: The owner reports continuing to see an unknown quantity of live fleas on the dogs. The pets were bathed with TropiClean Natural Flea Shampoo. There are 2 other dogs in the home (19US061601). Fleas are seen in the home and biting the owner as well. The dogs are inside/ outside. Pest control comes on a regular basis, the last treatment date is unknown. The owner reports seeing opossums and outdoor cats in the neighborhood. No further medical information expected.
16-Oct-2019	UAE; 19US061601; CA; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 45 - 88 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Jul-2019	22-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for 2 dogs,45 to 88 pounds, all other signalments unknown. 21 Jan 2018*: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 45-88 LBS (R61201BR) to the skin between the shoulder blades of each dog monthly for the first time. 21 Jul 2019: A dose was applied. 22 Jul 2019*: The owner saw an unknown quantity of live fleas on all the dogs. 1 dogs had a heavier burden than the other. 21 Sep 2019: A dose was applied. 16 Oct 2019: The owner reports continuing to see an unknown quantity of live fleas on the dogs. The pets were bathed with TropiClean Natural Flea Shampoo. There are 3 other dogs in the home (19US061587). Fleas are seen in the home and biting the owner as well. The dogs are inside/ outside. Pest control comes on a regular basis, the last treatment date is unknown. The owner reports seeing opossums and outdoor cats in the neighborhood. No further medical information expected.

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16-Oct-2019	UAE; 19US061604; WV; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 11.0 - 18.0 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Oct-2019*	06-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for 3 canines, from 2 to 10 years old, and 11.0 to 18.0 pounds, of further unknown signalment. 5 Oct 2019*: The pet owner applied 1 dose per dog of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, Package Unavailable), between the shoulder blades, in one spot. 6 Oct 2019*: The pet owner noticed that the dogs were scratching themselves. She then saw 1 to 4 fleas on the 3 dogs. 12 Oct 2019*: The pet owner bathed the dogs in Dawn dish soap. The pet owner continues to see fleas, although she is not seeing any fleas in the home. The dogs have access to a fenced in grassy yard. The yard was treated with an unknown pesticide on an unknown date. There is another dog in the home that also receives FRONTLINE PLUS DOG, but no fleas have been seen on the dog. The dogs have received FRONTLINE PLUS DOG 5-22 LBS previously, monthly since an unknown date. No further medical information expected.
16-Oct-2019	UAE; 19US061608; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for 2 felines of further unknown signalment. UNKNOWN DATE: The pet owner found an unknown number of fleas on the cats. 01 Oct 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (F41006AW) topically between the shoulder blades. 02 Oct 2019* to 16 Oct 2019: The owner continues to see an unknown number of fleas on the cats daily. The cats scratch from the fleas daily. The cats are indoor only. There are strays and wildlife in the environment as the owner lives in the country. There is carpet and hardwood in the home. The owner has washed the bedding and vacuums daily. There are no other pets in the home. It is unknown if owner has used FRONTLINE prior to this application. The cats have not been bathed. No further medical information expected.
16-Oct-2019	UAE; 19US061619; OR; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Oct-2019	14-Oct-2019*	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for a 4 years old, 8 pound canine of unknown breed. 4 Sep 2019: The pet began receiving FRONTLINE PLUS DOG 5-22 LBS (R62514BL), applied 1 vial topically between the shoulder blades for the first time this season. The pet is treated seasonally from Sep-Nov. 4 Oct 2019: Owner applied another dose. 14 Oct 2019*: The owner noticed a small amount of fleas on the pet. The owner has not been noticing fleas off of the pet inside the home. The yard is wooded with cedar trees. No further medical information expected.
16-Oct-2019	UAE; 19US061621; IN; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 25 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	21-Jul-2019	16-Oct-2019*	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for Chewy, a 25 pound, canine of further unknown signalment. Unknown date: The reporter began finding an unknown volume of fleas on the dog. It's unknown if fleas were also seen in the home. 21 Jul 2019: An unknown duration after initially finding fleas on the dog, the reporter applied one vial of FRONTLINE PLUS DOG 23-44 LBS (FL+) (S62406AX) topically between the shoulder blades. It's unknown if fleas were seen at the time of product

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						Cutaneous **Was the product used ok?:** Yes					application and it's unknown if Chewy has previously received FL+. Unknown date: An unknown duration following initial FL+ application, the reporter was still finding an unknown volume of fleas on Chewy. 21 Aug 2019 and 21 Sep 2019: One vial of FL+ was applied in like fashion and like before, it's unknown if fleas were present at the time of product application. Presently, the reporter continues find an unknown volume of fleas on Chewy. There is a second dog in the home that has also received FRONTLINE PLUS and is experiencing a similar flea issue. Please see case 19US061627. Both dogs stay primarily indoors, but do go outside in an unknown environment for bathroom breaks, and Chewy goes to an unknown park daily. The reporter was difficult to get information from and she ultimately refused to provide any additional details regarding the flea issue, conditions of the internal environment, and conditions of the external environment. No further medical information expected.
16-Oct-2019	UAE; 19US061626; -; U.S.A	**Species:** Canine **Breed:** Papillon **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 12 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Oct-2019	13-Oct-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the owner reported the following event for a Pappillon weighing 12 pounds (all other signalments unknown). 9 Oct 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S60810AX) was applied between the shoulder blades. 13 Oct 2019: The pet presented to the groomer and noted a large number of fleas. This was the first time fleas were noted. 14 Oct 2019*: The dog presented to the clinic and was treated with Capstar. 16 Oct 2019: The issue is still ongoing. The dog has access to a fenced in yard. The dog has received the product monthly since 1 Apr 2019 with no issue. There is one other dog using a different weight and experiencing an issue (see case 19US061636). No further medical information is expected.
16-Oct-2019	UAE; 19US061627; IN; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 14 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Jul-2019	16-Oct-2019*	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for Ziggy, a 14 pound, canine of further unknown signalment. Unknown date: The reporter began finding an unknown volume of fleas on the dog. It's unknown if fleas were also seen in the home. 21 Jul 2019: An unknown duration after initially finding fleas on the dog, the reporter applied one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (S61902AL) topically between the shoulder blades. It's unknown if fleas were seen at the time of product application and it's unknown if Ziggy has previously received FL+. Unknown date: An unknown duration following initial FL+ application, the reporter was still finding an unknown volume of fleas on Ziggy. 21 Aug 2019 and 21 Sep 2019: One vial of FL+ was applied in like fashion and like before, it's unknown if fleas were present at the time of product application. Presently, the reporter continues find an unknown volume of fleas on Ziggy. There is a second dog in the home that has also received FRONTLINE PLUS and is experiencing a similar flea issue. Please see case 19US061621. Both dogs stay primarily indoors, but do go outside in an unknown environment for bathroom breaks. The reporter was difficult to get information from and she ultimately refused to provide any additional details regarding the flea issue, conditions of the internal environment, and conditions of the external environment. No further medical information expected.

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ED_005739D_00014391-00349

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
16-Oct-2019	UAE; 19US061636; -; U.S.A	**Species:** Canine **Breed:** Pointer (German Short-Haired) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 80 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Oct-2019	13-Oct-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the owner reported the following event for a German Shorthaired Pointer weighing 80 pounds (all other signalments unknown). 9 Oct 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (S60501AX) was applied between the shoulder blades. 13 Oct 2019: The pet presented to the groomer and noted a large number of fleas. This is the first time fleas were noted on the pet. 14 Oct 2019*: The dog presented to the clinic and was treated with Capstar. 16 Oct 2019: The issue is still ongoing. The dog has access to a fenced in yard. The dog has received the product monthly since 1 Apr 2019 with no issue. There is one other dog using a different weight and experiencing an issue (see case 19US061626). No further medical information is expected.
16-Oct-2019	UAE; 19US061637; IL; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	13-Aug-2019	16-Oct-2019*	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for a 1 year old, 10 pound Domestic Longhair feline of unknown reproductive status. 1 Aug 2019*: The owner noticed a moderate amount of fleas on the pet. 13 Aug 2019: The pet began receiving FRONTLINE CATS (Lot unknown) (package unavailable), applied 1 vial topically between the shoulder blades for the first time. 12 Sep 2019: Owner applied monthly dose. 12 Sep 2019*: Owner continues to see fleas. 13 Oct 2019: Owner applied monthly dose. 16 Oct 2019: Owner continues to remove a moderate amount of fleas off the pet. The owner has not been noticing fleas off of the pet inside the home. The cat is indoor/outdoor. There a total of 1 canine and 1 feline in the household. See case 19US061713. The yard is fenced with bushes. No further medical information expected.
16-Oct-2019	UAE; 19US061638; MA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Oct-2019*	11-Oct-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for a feline of unknown signalment. 11 Oct 2019*: The pet owner noticed the cat was itching. He applied 1 dose of FRONTLINE PLUS CAT (S40210, invalid lot), in one spot, between the shoulder blades. Unknown date: The pet owner bathed the cat with an unknown shampoo. The pet owner is still seeing fleas on the cat. The cat goes outside, and no fleas have been seen in the home. There are no other pets in the home. The cat previously received 1 dose of FRONTLINE PLUS CATS on approximately 23 Sep 2019* and has been treated monthly since an unknown amount of time. No further medical information expected.
16-Oct-2019	UAE; 19US061647; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Neutered **Age:** - **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	06-Oct-2019	10-Oct-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for a 10 pound feline of unknown signalment. 6 Oct 2019: The pet began receiving FRONTLINE PLUS CAT (Lot unknown)(package unavailable), applied 1 vial topically between the shoulder blades for the first time. 10 Oct 2019*: The owner found an attached, alive tick. The environment is unknown. The tick species in unknown. No further medical information expected.

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ED_005739D_00014391-00350

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					
16-Oct-2019	UAE; 19US061649; WA; U.S.A	**Species:** Canine **Breed:** Mastiff **Sex:** X **Sex qualifier:** - **Age:** 6.00 Week(s) **Weight:** 25 lbs	4	4	4	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Oct-2019	08-Oct-2019	1 Day(s)	D-A	Suspected Adverse Event: On the 16 Oct 2019, a pet owner reported the following event for a total of 4 puppies, 25 pounds, 6 weeks old (born 26 Aug 2019), mixed sex, intact, non-pregnant, non-lactating, Mastiff. 7 Oct 2019: The pet owner applied to the nursing mom for the first time 1 dose of FRONTLINE PLUS DOG 89-132 LBS (S62311AX), topically between the shoulder blades. 8 Oct 2019: 1 puppy could not move, lethargic, crying in pain, panting, hyper salivating and disoriented, ataxia. Throughout the day the puppy had about 12 episodes with the symptoms described above that the owner saw. Later that day the puppy was anorexic and adipsic. The pet owner forced water with a syringe to keep the puppy hydrated. 9 Oct 2019: The symptoms continued and the dog was euthanized. This day another puppy in the litter experienced the same symptoms and it was also euthanized. 10 Oct 2019: The third and fourth puppy in the litter experienced the same issues. The owner presented the puppies to the veterinarian who performed a parvo test which was negative. The veterinarian mentioned that the puppies showed symptoms of toxicity. The puppies were not treated with any medications. 16 Oct 2019: The remaining 2 puppies were euthanized. The pet owner strongly believes that the FRONTLINE PLUS caused this reaction to the puppies since they had not received any other medication or vaccines in the past only the only thing that they have had exposure to is the FRONTLINE PLUS through the mom who was nursing them and the owner had applied it to her on the 7 Oct 2019. The nursing mom is showing symptoms of tremors see case 19US061655. No further medical information expected. UPDATE 25 NOV 2019: Add Death VeDDRA code.
16-Oct-2019	UAE; 19US061655; WA; U.S.A	**Species:** Canine **Breed:** Mastiff **Sex:** F **Sex qualifier:** Pregnant Lactating **Age:** 20.00 Month(s) **Weight:** 90 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Tobramycin; Optimune; Opti X care; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Oct-2019	09-Oct-2019*	2 Day(s)	D-D	Suspected Adverse Event: On the 16 Oct 2019, a pet owner reported the following event for Sadie, a 90 pound, 20 month old (born 1 Feb 2018), intact, female nursing, Mastiff. 7 Oct 2019: The pet owner applied for the very first time 1 dose of FRONTLINE PLUS DOG 89-132 LBS (S62311AX) topically between the shoulder blades. 9 Oct 2019*: The pet owner noticed that the dog was trembling every time she would check on her. The dog was not eating like she normally does but was drinking water fine. The dog has not been seen by a veterinarian and has not received any treatment. The dog was diagnosed with dry eye and an eye ulcer so she is currently on Tobramycin, Optimune and Opti X care ophthalmic lotion since 7 Oct 2019. The issue is ongoing. The owner reported another case for the puppies see case 19US061649. No further medical information expected.
16-Oct-2019	UAE; 19US061666; -; U.S.A	**Species:** Canine **Breed:** Dachshund **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	01-Sep-2019	15-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the owner reported the following event for a 15 pound, Dachshund (all other signalments unknown). 1 Aug 2019: Started on monthly doses of FRONTLINE PLUS DOG 5-22 LBS (S61203AX) topically, between the shoulder blades, by the owner. 15 Sep 2019*: The owner started seeing a small amount of fleas on the dog, but a large amount of flea dirt.

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ED_005739D_00014391-00351

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** Yes					1 Oct 2019*: Most recent dose of FRONTLINE was applied. The owner is still finding a small amount of fleas on the dog and a lot of flea dirt. The owner is not seeing fleas in the home. The dog goes outside for potty breaks in an open yard with trees, bushes, and a deck. No further medical information expected.
16-Oct-2019	UAE; 19US061695; IA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 35 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Aug-2019	12-Oct-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On Oct 16 2019 the owner reported the following event for an unknown canine, 1 year old, 35 pound*, intact female. 7 Aug 2019: The owner applied one vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown, package unavailable) topically between the shoulder blades for the first time. 28 Sep 2019: The owner applied FRONTLINE PLUS to the pet. 6 Oct 2019: The owner found one live tick crawling on the pet. 12 Oct 2019: The owner noticed a few ticks crawling on the pet. It is unknown if the owner removed the ticks from the pet. It is unknown if ticks were seen prior to application. The pet has access outside and is leash walked in the woods. The owner brings the pet to local dog parks. The pet is brought to the groomers on unknown dates and bathed with unknown shampoos. There is a cat in the home see case 19US062017. It is unknown if the pet is in good health or if she has a history of reactions. No further medical information expected.
16-Oct-2019	UAE; 19US061742; PA; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 13 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Oct-2019	12-Oct-2019	1 Day(s)	D-D	Suspected Adverse Event: On 16 Oct 2019, the owner reported the following event for Sophia, a 7 year old, 13 pound, spayed female Yorkie/ Poodle (toy) mix. 11 Oct 2019: One vial of FRONTLINE PLUS 5-22 LBS (S611412AL) was applied to the skin between the shoulder blades for the first time. 12 Oct 2019: The dog started to itch all over. 13 Oct 2019: The dog had hair loss at her neck, top of her head, and on her backside. 16 Oct 2019: The dog was taken to the vet and given two injections of antibiotics. No further information available.
17-Oct-2019	UAE; 19US061771; MA; U.S.A	**Species:** Canine **Breed:** Wheaton Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 60 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown allergy shot; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jan-2012*	03-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019 the owner reported the following event for Scooter a, 7 year old, 60 pound, neutered male, Wheaton Terrier. 1 Jan 2012* through 1 Jul 2019*: The owner applied one vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) topically between the shoulder blades monthly, year round. 2 Aug 2019: The owner applied FRONTLINE PLUS to the pet. 2 Sep 2019: The owner applied FRONTLINE PLUS to the pet. 23 Sep 2019*: The pet became itchy, due to seasonal allergies. The owner presented the pet to the veterinarian. The pet was treated with an unknown allergy shot. 1 Oct 2019: The owner applied FRONTLINE PLUS to the pet. 3 Oct 2019: The pet was brought to the groomer to be bathed. The owner noticed 3 fleas on the pet when he came home from the groomer. 17 Oct 2019: The owner noticed one flea on the pet. The pet has access outside to a large yard, where urban wildlife is present. The pet is leash walked in the park and fairgrounds. There are no other pets in the home. The owner does not see fleas in the home. The pet has no history of reactions and suffers from

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ED_005739D_00014391-00352

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											seasonal allergies. No further medical information expected. UPDATE 6 Dec 2019: The pet owner reported the dog still had fleas and used Advantix and no longer has fleas now. No further medical information expected.
17-Oct-2019	UAE; 19US061776; MA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Sep-2019	17-Oct-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019 the owner reported the following event for Leo a 2 year old*, 8 pound*, neutered male, unknown feline. 30 Aug 2019: The owner applied one vial of FRONTLINE PLUS CATS (S41004AW) topically between the shoulder blades for the first time. There were no ticks seen prior to application as the pet was indoor only. 1 Sep 2019: The pet began to go outside for recreation. 30 Sep 2019: The owner applied FRONTLINE PLUS to the pet. 17 Oct 2019: The owner noticed a live tick crawling on the pets chin. The owner removed the tick. No other ticks seen on pet. The pet has access outside to a wooded area and grass yard. There is another cat in the home not currently on flea and tick preventative and is indoor only. It is unknown if the pet is bathed. The pet was in good health and has no history of reactions. No further medical information expected.
17-Oct-2019	UAE; 19US061821; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 9 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Apr-2019*	06-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019 a pet owner reported the following event for Lucky, a 9 pound female dog of unknown other signalment. Apr 2019*: Owner started seeing fleas on the dog and applied FRONTLINE PLUS DOG 5-22 LBS (S61902AL) to the skin between the animal's shoulder blade first time of the season. 6 Apr 2019*: Owner continuing to see 5-10 fleas a day on the dog. 5 Oct 2019: Most recent dose applied. The dog has had fleas since Apr 2019*. One inside cat in the home that uses FRONTLINE PLUS CATS and does not have fleas. The dog lives inside, going outside in a fenced grass yard to go potty where the owner does see wildlife. The yard has not been treated. Owner has fleas in the home and treated it with pesticide spray. The dogs are bathed once every 6 months with an unknown dog shampoo. The owner uses the product seasonally for an unknown number of years. There is one other dog in the home who has her own case: 19US061873. No further medical information expected.
17-Oct-2019	UAE; 19US061853; GA; U.S.A	**Species:** Canine **Breed:** Dachshund (Miniature) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Aug-2019*	10-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the owner reported the following event for Daisy, a 4 year old, 10 pound, spayed female Dachshund (miniature). * 3 Aug 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (FL) (lot unknown, packaging unavailable) was given topically to the skin between the shoulder blades. *Unknown date: The dog started to pick up fleas. *Unknown date: The dog was bathed in Dawn. *3 September 2019: The dog still had fleas and another application of FL was given. *3 Oct 2019: The dog still had fleas and another application of FL was given. The dog is picking a small to medium number of fleas. The dog is strictly indoors, but has access to a screen in porch and the owner is not being bit inside the home. The dog is bathed every 2 weeks. No further information available.
17-Oct-2019	UAE; 19US061873;	**Species:** Canine **Breed:** Canine	1	1	0	**Product used:** FIPRONIL	05-Apr-2019*	06-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019 a pet owner reported the following event for Lady, a 30 pound female dog of

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	-; U.S.A	(unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 30 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					unknown other signalment. Apr 2019*: Owner started seeing fleas on the dog and applied FRONTLINE PLUS DOG 23-44 LBS (lot unknown, package unavailable) to the skin between the animal's shoulder blade first time of the season. 6 Apr 2019*: Owner continuing to see 5-10 fleas a day on the dog. 5 Oct 2019: Most recent dose applied. The dog has had fleas since Apr 2019*. One inside cat in the home that uses FRONTLINE PLUS CATS and does not have fleas. The dog lives inside, going outside in a fenced grass yard to go potty where the owner does see wildlife. The yard has not been treated. Owner has fleas in the home and treated it with pesticide spray. The dogs are bathed once every 6 months with an unknown dog shampoo. The owner uses the product seasonally for an unknown number of years. There is one other dog in the home who has her own case: 19US061821. No further medical information expected.
17-Oct-2019	UAE; 19US061906; FL; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-May-2019	02-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the owner reported the following event for Smokey, 1 year old, 8 pounds, neutered male, Domestic Shorthair. 1 May 2019: The cat started on FRONTLINE PLUS on a monthly basis. 1 Sept 2019: One vial of FRONTLINE PLUS CATS (S41004AW) was applied between the shoulder blades, by the pet owner. 2 Sept 2019*: The cat had fleas for the first time. 1 Oct 2019: The most recent dose of the product was applied. Fleas were still seen on the cat. Small amount of fleas. The cat does not get bathed. The owner is not seeing any flea activity in the household. The home gets monthly treatments from a pest control facility. The cat is indoor only. No further medical information is expected.
17-Oct-2019	UAE; 19US061914; NJ; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 11 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	13-Oct-2018*	17-Oct-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the owner reported the following event for a 11 pound dog (signalment unknown). 13 Oct 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S60302AL) was applied topically to the skin between the shoulder blades. 17 Oct 2019: The dog was taken to the groomer who found a large number of fleas on the dog. The dog is treated with FL monthly and the owner has never seen fleas. The dog is bathed every other month and the environment she is exposed to is unknown. There are no other pets in the home. No further information.
17-Oct-2019	UAE; 19US061916; MI; U.S.A	**Species:** Canine **Breed:** Havanese **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 12 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-May-2019*	02-May-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019 a pet owner reported the following event for Bella, a 12 pound, female Havanese of unknown other signalment. Jan 2019*: Owner started seeing fleas on the dog. 1 May 2019*: Started applied FRONTLINE PLUS DOG 5-22 LBS (lot unknown, Package unavailable) to the skin between the animal's shoulder blades for the first time of the season. 2 May 2019*: Owner still seeing fleas on the dog. 1 Oct 2019: Most recent application. Owner has continued to see fleas on the dog since 2 May 2019*. There is a cat in the house who owner says does not have fleas and owner is only using fleas spray on him. Owner used flea spray in the home. The dog lives inside, going outside for potty breaks in

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											a fenced grass yard. The yard has not been treated. It is unknown if there is wildlife in the yard. Owner uses the product seasonally for an unknown number of years. No further medical information expected.
17-Oct-2019	UAE; 19US061917; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 72 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	11-Oct-2019	10-Oct-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the owner reported the following event for an unknown canine, all other signalment unknown 1 Oct 2019: One vial of the FRONTLINE PLUS DOG 45-88 LBS (Lot unknown, reported not queried) was applied topically in between the shoulder blades by the owner. The owner purchased an unknown amount at an unknown date. 10 Oct 2019: The owner noticed 5 ticks walking in the dog. The dog is indoor mostly and has access to an open area. This is the first dose for the dog. No further medical information is expected.
17-Oct-2019	UAE; 19US061921; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	26-Sep-2019	03-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the pet owner reported the following event for 2 canines of further unknown signalment. 2016*: The pet owner began applying 1 full vial of FRONTLINE PLUS DOG 45-88 LBS (S61202AX) between the shoulder blades monthly. 26 Sep 2019: The most recent dose was applied. 03 Oct 2019: The dogs presented to the veterinarian and fleas were found on the dogs. The dogs were bathed with flea shampoo. 04 Oct 2019 to 17 Oct 2019: The owner continues to see anywhere from 3-6 fleas on the dogs daily. There are also 2 cats in the home, reference case 19US061935. The dogs are indoor and go outside to use the bathroom and for walks. There is hardwood only in the home. The owner is seeing fleas in the home. The owner has flea bombed and treated the home. The owner has washed the bedding. There is another cat in the neighborhood that comes through yard. No further information expected.
17-Oct-2019	UAE; 19US061926; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 45 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jul-2019*	02-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the owner reported the following event for a 45 pound canine (all other signalments unknown). Unknown date: Started on monthly doses of FRONTLINE PLUS DOG 45-88 LBS (S62202AX) topically between the shoulder blades, by the owner, on a year round basis (usually on the 1st of each month). Jul 2019*: The owner started seeing fleas on the dog. Sep 2019*: The owner bathed the dog with Dawn dish soap. 17 Oct 2019: Most recent dose of FRONTLINE was applied. The owner is still seeing a small amount of fleas on the dog. The owner is not seeing fleas in the home. The owner treated the home and the yard with an unknown product. The dog goes outside for potty breaks in a fenced in yard with trees and a deck. The owner usually bathes the dog every 2 months with a product called Crazy Dog. There is another dog in the home treated with FRONTLINE (see case 19US061933). No further medical information expected.
17-Oct-2019	UAE; 19US061929;	**Species:** Canine **Breed:** Canine	2	2	0	**Product used:** FIPRONIL	01-Oct-2018	02-Aug-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019 the owner reported the following event for Phinneus a 1 year old*, 7 pound*,

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ED_005739D_00014391-00355

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	OR; U.S.A	various breeds **Sex:** M **Sex qualifier:** - **Age:** 1.00 Year(s) **Weight:** 7 - 13 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					intact male, Papillon and Bentley a 1 year old*, 13 pound*, intact male, King Charles Cavalier. 1 Oct 2018 through 1 Aug 2019: The owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS (S61203AX) topically between the shoulder blades monthly, year round to each pet. 1 Aug 2019*: The owner noticed 1 to 2 fleas* on the pets after application of FRONTLINE PLUS. 1 Sep 2019: The owner applied FRONTLINE PLUS to the pets. 1 Oct 2019: The owner applied FRONTLINE PLUS to the pets. 2 Oct 2019*: the owner noticed 3 to 4 fleas* and a lot of flea dirt on the pets. 9 Oct 2019*: The pets were bathed with Ivory dish soap. There were 5 to 6 dead fleas* seen in bath water after bath. The pets have access outside to a grass yard, where urban wildlife is present. The pets are leash walked in the neighborhood, where other pets are also leash walked. The pets go to the groomer every other month. There are no other pets in the home. The pets were in good health prior to application and have no history of reactions. No further medical information expected.
17-Oct-2019	UAE; 19US061935; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	26-Sep-2016*	03-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the pet owner reported the following event for 2 felines of further unknown signalment. 2016*: The pet owner began applying 1 full vial of FRONTLINE PLUS CATS (S40601AX) between the shoulder blades monthly. 26 Sep 2019: The most recent dose was applied. 03 Oct 2019: The cats presented to the veterinarian and fleas were found on the cats. The cats were bathed with flea shampoo. 04 Oct 2019 to 17 Oct 2019: The owner continues to see anywhere from 3-6 fleas on the cats daily. There are also 2 dogs in the home, reference case 19US061921. The cats are indoor and go outside to use the bathroom and for walks. There is hardwood only in the home. The owner is seeing fleas in the home. The owner has flea bombed and treated the home. The owner has washed the bedding. There is another cat in the neighborhood that comes through yard. No further information expected.
17-Oct-2019	UAE; 19US061941; PA; U.S.A	**Species:** Canine **Breed:** Bulldog **Sex:** M **Sex qualifier:** - **Age:** 8.00 Year(s) **Weight:** 65 lbs	4	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Oct-2019	08-Oct-2019*	3 Day(s)	D-C	Suspected Adverse Event: On 17 Oct 2019, the pet owner reported the following event for Dozer, a 8 year old, 65 pound, intact male, Bulldog. Unknown date: The dog began receiving one vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) monthly. The product was applied directly on the skin between the shoulder blades. 5 Oct 2019: The most recent date of application. 8 Oct 2019*: The dog began experiencing signs of lethargy. The dog has not been to the veterinary clinic. No treatments have been provided. The dog's current condition is ongoing. The dog previously received FRONTLINE PLUS with no previous adverse effects. There are three other dogs in the home, who are also treated with FRONTLINE PLUS, with no adverse events. No further medical information expected.
17-Oct-2019	UAE; 19US061949; CA; U.S.A	**Species:** Canine **Breed:** Terrier Breeds (500 Series) **Sex:** U	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	10-Oct-2019*	17-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the pet owner reported the following event for 2 Terrier mixed dogs, ranging 50-65 pounds, with otherwise unknown signalment. 16 Jul 2019: The dogs received FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) for the first time with

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ED_005739D_00014391-00356

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** 50 - 65 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					unknown purchase history. Product application details are unknown. Fleas were not seen prior to product application. 10 Oct 2019*: The pet owner began seeing fleas. Another dose was applied to both dogs. 17 Oct 2019: The owner is still noticing an unknown amount of fleas. The dogs' excursion details are unknown. The dogs have not presented to the veterinary clinic. No treatments have been provided at home. The dogs' current condition is ongoing. There are no other animals in the household. No further medical information expected.
17-Oct-2019	UAE; 19US061952; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 8.000 - 10 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Oct-2019*	16-Oct-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 17 Oct 2019, the owner reported the following event for a feline weighing between 8-10 pounds. 16 Oct 2019: The cat was itching and had fleas. One vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) was applied between the shoulder blades. 17 Oct 2019: The itching worsened. The owner continued to find fleas. It is unknown if there are any other pets in the home. The cat's environment is unknown. The cat received the FRONTLINE monthly since Aug 2019*. No further medical information is expected.
17-Oct-2019	UAE; 19US061965; OH; U.S.A	**Species:** Canine **Breed:** Pomeranian **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 20 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown flea shampoo; unknown oatmeal shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Aug-2016	05-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the pet owner reported the following event for Buddy, a 5 year old*, 20 pound, neutered male, Pomeranian mix. 2016 (unknown date): The canine began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (lot unknown; package unavailable) applied topically between the shoulder blades. One vial has since been applied in the same fashion, monthly year-round on the fourth. Fleas have never been present at the times of FL+ application nor has the reporter ever seen fleas on Buddy throughout this period of time. 4 Aug 2019: One vial of FL+ (S61412AL) was applied and it's unknown if fleas were present at the time of application. Unknown dates: An unknown duration following the Aug FL+ application, the canine began pruritic where he was seen chewing himself; however, fleas were not seen at the time of symptom onset. 4 Sep 2019: A second vial of FL+ was applied at which time, Buddy was still pruritic. It's unknown if fleas were present when FL+ was applied. Unknown dates: An unknown duration following FL+ application, the reporter finally noticed an unknown volume of flea dirt and live fleas on Buddy. Upon noticing the presence of fleas, the reporter bathed the canine with an unknown flea shampoo which then caused Buddy to break out. The reporter provided no further description of the clinical signs exhibited and it's unknown if Buddy ever subsequently recovered. Shortly after that bath, he was taken to a local pet store where he was bathed in an unknown oatmeal shampoo to soothe the ongoing pruritus caused by the presence of fleas. 4 Oct 2019: A third application of FL+ was administered and it's unknown if fleas were present at that time. Unknown date: An unknown duration following product use, the

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ED_005739D_00014391-00357

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											reporter was finding a medium volume of fleas on Buddy. Presently, Buddy is still pruritic and continues to pick up a medium volume of fleas. The reporter has not seen any fleas in the home. There are no other
17-Oct-2019	UAE; 19US061983; KY; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 10.8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Aug-2019	17-Oct-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the owner reported the following event for Ben, 10.8 pound Male, neutered, 7 year old, Yorkshire Terrier 1 Oct 2019: One vial of the FRONTLINE PLUS DOG 5-22 LBS (Lot unknown, package unavailable) was applied in between the shoulder blades by the owner. 17 Oct 2019: The owner noticed flea dirt on the pet but no live fleas were seen. There are no visiting pets within the home and no wildlife has been seen in the area. No indoor fleas were seen. This is the only pet within the home.This is the second dose of the product for the pet this season. No further medical information is expected.
17-Oct-2019	UAE; 19US061989; CA; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** - **Age:** 7.00 Year(s) **Weight:** 75 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Sep-2019	18-Sep-2019	1 Day(s)	D-C	Suspected Adverse Event: On 17 Oct 2019, the owner reported the following event for Sophia, 7 years old, 75 pounds, non-pregnant non- lactating, German Shepherd/ Husky crossbreed. 17 Sept 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades, by the pet owner. 18 Sept 2019: The dog had diarrhea. 17 Oct 2019: The dog still continues to have diarrhea and now is dehydrated. The owner scheduled a Vet appointment for 21 Oct 2019. No further medical information is expected.
17-Oct-2019	UAE; 19US061993; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 3 lbs	3	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	26-Sep-2019	15-Oct-2019*	19 Day(s)	D-C	Suspected Adverse Event and Suspected Lack of Efficacy: On 17 Oct 2019, the owner reported the following event for a 4 months old, 3 pound, intact feline (all other signalments unknown). 26 Sept 2019: The owner notice fleas. An unknown amount of FRONTLINE SPRAY (lot unknown, package unavailable) was applied over the pet. 15 Oct 2019*: The owner noticed more fleas. The owner poured an unknown amount of FRONTLINE SPRAY over the cat. After an unknown period of time the cat experienced lethargy, inability to walk, and jumpy nerves. The pet did not present to the clinic and no treatment was provided. 16 Oct 2019: The cat recovered. There are 3 other cats in the home that received the product. One of those cats also experienced symptoms (see case 19US062727). No further medical information is expected. UPDATE 30 Oct 2019: The Outcome of reaction field was corrected to Recovered per case info. No further medical information is expected.
16-Oct-2019	UAE; 19US061997; MI; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other	01-Oct-2019*	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019, the pet owner reported the following event for 3 felines of further unknown signalment. Unknown date: The pet owner applied an unknown amount of FRONTLINE PLUS CATS(unsubstantiated) in an unknown location to each cat. The pet owner continues to see fleas and flea dirt on the cats.

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ED_005739D_00014391-00358

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products **Route:** unknown **Was the product used ok?:** Unknown to Company					It is unknown if fleas were seen prior to application. No specific details are available. No further medical information expected.
17-Oct-2019	UAE; 19US061998; MD; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2017*	17-Oct-2019*	16 Day(s)	D-C	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the pet owner called and reported the following for a canine of unknown signalment. 2017*: Pet owner applied FRONTLINE PLUS DOG 5-22 LBS (unsubstantiated) (lot unknown, reporter refused) monthly. An unknown volume per animal via an unknown route at an unknown location. 17 Oct 2019*: Pet owner reports the dog tested positive for an unknown tick borne disease via an unknown test. It is unknown if the test was routine. It is unknown is the dog was showing any signs. It is unknown if any treatments have been administered. Their current condition is ongoing. It is unknown what environment the canine frequents. It is unknown if the owner bathes the canine. It is unknown if there are any other pets in the household. This is the extent of information known as caller refused to report. No further medical information expected.
17-Oct-2019	UAE; 19US062013; CA; U.S.A	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** F **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 21 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Oct-2019	17-Oct-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the pet owner reported the following event for Bethany, a 14 year old*, 21 pound*, spayed female, Jack Russell Terrier mix. 14 Oct 2019: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (S61902AL). This was the first dose of product used. The product was applied directly on the skin between the shoulder blades. No fleas were seen prior to product application. 17 Oct 2019: The owner noticed one flea, and the dog scratching some. The dog has access to a fenced in yard, and does go on leash walks. No treatments have been provided at home. The dog's current condition is ongoing. There is another dog in the household, who is on FRONTLINE PLUS, with no fleas reported. The dog has a history of a vaccine reaction to an unknown Rabies vaccine in 2015. No further medical information expected.
17-Oct-2019	UAE; 19US062015; NJ; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Jul-2019	17-Oct-2019	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019, the pet owner reported the following event for 2 felines of unknown signalments. 27 Jul 2019: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (S41305AW) to the skin between the shoulder blades monthly for the first time after seeing an unknown quantity of live fleas. 17 Sep 2019: The owner applied a dose. 17 Oct 2019: The owner reports the flea burden gets better for 1 week post product application then becomes the same as it previously was. The owner continues to see live fleas on the cats. There are no other pets in the home. The cats are indoors only. There is no prior history of skin conditions. No baths have been given to either pet. The owner reports the house has been sprayed with an unknown flea treatment. No fleas are seen in the home. No further medical information expected.
16-Oct-2019	UAE; 19US062017;	**Species:** Feline **Breed:** Feline	1	1	0	**Product used:** FIPRONIL	07-Oct-2019	13-Oct-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Oct 2019 the owner reported the following event for a feline of unknown signalment.

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ED_005739D_00014391-00359

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	IA; U.S.A	(unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					3 Sep 2019:The owner applied one vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) topically between the shoulder blades for the first time. 7 Oct 2019: The owner applied FRONTLINE PLUS to the pet. 11 Oct 2019: The owner noticed an unknown number of ticks crawling in the pets kennel., where the pet has been sleeping through the night. 13 Oct 2019: The owner noticed an unknown number of ticks crawling on the pet. It is unknown if ticks were seen prior to application. It is unknown if the owner removed the ticks from the pet. The pet has access outside to the woods where urban wildlife is present. It is unknown if the pet is bathed. There is a dog in the home see case 19US061695. The health of the pet is unknown. No further medical information is expected.
18-Oct-2019	UAE; 19US062024; WV; U.S.A	**Species:** Canine **Breed:** Great Pyrenees **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 65 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Sep-2019	18-Oct-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Oct 2019 the owner reported the following event for Reece, a 11 year old, 65 pound*, spayed female, Great Pyrenees Border Collie cross. 30 Jan 2010* through 30 Aug 2019*: The owner applies on vial of FRONTLINE PLUS DOG 45-88 LB (S62408AXR) topically between the shoulder blades monthly, year round. 30 Sep 2019: The owner applied FRONTLINE PLUS to the pet. 1 Oct 2019: The owner noticed one tick on the pet. The owner removed the live tick form the pet. The species of tick is unknown. 8 Oct 2019: The owner took 2 ticks* off the pet. The owner removed the live ticks. The species of tick is unknown. 14 Oct 2019: The owner removed 4 engorged live ticks from the pet. The species of tick is unknown. 18 Oct 2019: The owner removed one live engorged tick from the pet. The species of the tick is unknown. The pet has access outside, where she is walked in the woods. There is deer, bear, raccoon, possum and chipmunks present in the area. There are no other pets in the home. It is unknown if the pet is bathed. No further medical information expected.
18-Oct-2019	UAE; 19US062036; PA; U.S.A	**Species:** Canine **Breed:** Pointer (German Short-Haired) **Sex:** M **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** 67 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Sep-2019	12-Sep-2019*	N/A	D-C	Suspected Adverse Event: On 18 Oct 2019 a pet owner reported the following event for Kubota, a 67 pound, 4 yearold, intact male German Shorthair Pointer. 9 Sep 2019: Owner applied FRONTLINE PLUS DOG 45-88 LBS (S62408AX) to the skin between the animal's shoulder blades. 12 Sep 2019*: Dog developed diffuse hives on dorsum, which broke open an unknown amount of days later. Dog very pruritic. Owner started feeding salmon and coconut oil. Did not take dog to a veterinarian. 7 Oct 2019*: Sores from broken open hives almost resolved. 9 Oct 2019: Owner applied FRONTLINE PLUS. 10 Oct 2019: Dog developed diffuse hives on dorsum, which broke open an unknown amount of days later. Dog very pruritic. Did not take dog to a veterinarian. The sores from the broken open hives are still present, but improving. No previous drug or vaccine reaction. Dog has Lyme disease, but asymptomatic. The dog has received FRONTLINE PLUS, monthly, year round for approximately 3.5 years without issue. No further medical information expected.
17-Oct-2019	UAE; 19US062041; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown)	1	1	1	**Product used:** FIPRONIL 10%/S	01-Aug-2019*	15-Aug-2019*	2 Week(s)	D-A	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 17 Oct 2019, the pet owner reported the following event for a 17 year old* cat with otherwise unknown signalment.

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ED_005739D_00014391-00360

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: U **Sex qualifier:** Unknown **Age:** 17.00 Year(s) **Weight:** Unknown				METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					1 Aug 2019*: The cat received FRONTLINE PLUS CATS (lot unknown, package unavailable) for the first time with unknown purchase history. The product was applied directly on the skin between the shoulder blades. Fleas were seen for 2 months prior to product application. 15 Aug 2019*: The owner still noticed an unknown amount of fleas. The cat is indoor/outdoor. 1 Sep 2019*: The cat passed away from unknown cause. It is unknown if the cat presented to the veterinary clinic. There is another dog in the home affected by fleas , see case 19US061865. No further medical information expected.
18-Oct-2019	UAE; 19US062053; -; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 75 lbs*	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Sep-2019	14-Oct-2019	29 Day(s)	D-A	Suspected Adverse Event: On 18 Oct 2019, the pet owner reported the following event for a 75 pound*, female, canine of further unknown signalment. Unknown date: The canine began receiving one vial of FRONTLINE PLUS DOG 45-88 LBS (FL+) (lot unknown; package unavailable) applied topically between the shoulder blades and a vial has since been applied monthly on the fifteenth. 15 Sep 2019: One vial of FL+ was applied in the same manner described above. 14 Oct 2019: The canine was euthanized. The reporter mentioned the information above in passing as the FL+ application history was relevant regarding an ongoing flea issue for a puppy in the home. The dog in this report never had fleas while receiving FL+. It's also unknown if any symptoms were exhibited prior to euthanasia. A report was also created for the puppy who is on NEXGARD. Please see case 19US062047. No other details regarding this patient and her health could be obtained. No further medical information expected.
18-Oct-2019	UAE; 19US062061; -; U.S.A	**Species:** Canine **Breed:** Blue Heeler **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 35 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn Dish Soap; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Sep-2019	25-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the pet owner reported the following event for Riley, a 6 year old, 35 pound, neutered male, Blue Heeler Mix. 9 Sep 2019 and 12 Oct 2019: The patient got their doses of FRONTLINE PLUS DOG 23-44 LBS (F61009AL), 9 Sep 2019 was the first dose of the year. The owner gives FRONTLINE to the dog usually every sporing and continues monthly until winter, exact dates are unknown. The owner purchased a 3 pack this past purchase, and the animal has used FRONTLINE in the past, exact dates are unknown. It was applied between the shoulder blades. No fleas were seen prior to the dosing of FRONTLINE. 25 Sep 2019*: The owner noticed fleas and still sees some today. 1 Oct 2019: The owner gave the dog a bath with Dawn Dish Soap. The pet goes outside very often. The pet is showing no skin issues, but is itching from the fleas. There are no fleas in the home, and no fleas on the owner. The patient's current condition is ongoing. No further medical information expected.
18-Oct-2019	UAE; 19US062083; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown	11-Oct-2019*	12-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the pet owner reported via email the following event for 2 cats of unknown signalment. 11 Oct 2019*: The owner applied FRONTLINE PLUS CAT (product unsubstantiated), by an unknown method. It is unknown when the owner began seeing fleas. It is unknown if the owner has been noticing fleas off of the pets inside the home . It is unknown if the pets are bathed. It is unknown if the pets have any skin issues. The environment is unknown. It is unknown if the

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ED_005739D_00014391-00361

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					pets have presented to the veterinarian. It is unknown if the pets are indoor/outdoor. There a total of 2 felines in the household. No further medical information expected.
18-Oct-2019	UAE; 19US062105; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 23 - 44 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Oct-2019*	06-Oct-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the pet owner reported the following event for 1 canine, 23-44 pounds, all other signalment unknown. 04 Oct 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 23-44 LBS (S61901AL) to the skin between the shoulder blades for the first time. 06 Oct 2019*: The owner noticed an unknown quantity of live fleas on the dog, noticeably on the face. 18 Oct 2019: The owner reports continuing to see an unknown greater quantity of live fleas on the dog. There are 2 other dogs in the home on FRONTLINE PLUS DOG 45-88 LBS (19US062114). The dog goes into the backyard for short periods of time. No baths have been given. The owner has not seen any urban wildlife or outdoor cats in the neighborhood. It is unknown if the owner is seeing fleas in the home. No further medical information expected.
18-Oct-2019	UAE; 19US062114; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 45 - 88 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Oct-2019*	06-Oct-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the pet owner reported the following event for 2 canines, 45-88 pounds, all other signalment unknown. 04 Oct 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 45-88 LBS (lot unknown/ package unavailable) to the skin between the shoulder blades of each dog for the first time. 06 Oct 2019*: The owner noticed an unknown quantity of live fleas on the dogs, noticeably on the face. 18 Oct 2019: The owner reports continuing to see an unknown greater quantity of live fleas on the dogs. There is 1 other dog in the home on FRONTLINE PLUS DOG 23-44 LBS (19US062105). The dogs go into the backyard for short periods of time. No baths have been given. The owner has not seen any urban wildlife or outdoor cats in the neighborhood. It is unknown if the owner is seeing fleas in the home. No further medical information expected.
18-Oct-2019	UAE; 19US062128; OR; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 33 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Oct-2018*	07-Oct-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the owner reported the following event for a 33 pounds, female, canine (all other signalments unknown). 2018*: The dog started on FRONTLINE PLUS on a monthly basis year round. 27 Sept 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown, package unavailable) was applied between the shoulder blades, by the pet owner. 7 Oct 2019: The dog had a small amount of fleas for the very first time. 14 Oct 2019: Another dose of the product was applied to the dog. The dog gets bathed once a month with an unknown oatmeal dog shampoo. The owner is not seeing any flea activity in the household. The owner is allergic to fleas. There are known wildlife in the area, raccoons and opossums. The dog has access to an unknown outdoor area for bathroom breaks. No further medical information is expected.
18-Oct-2019	UAE;	**Species:** Canine	3	3	0	**Product used:**	16-Oct-2019*	17-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the pet owner

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ED_005739D_00014391-00362

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19US062157; NY; U.S.A	**Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 60.0 lbs				FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					reported the following event for 3 canines that are 60.0 pounds*. All other signalments are unknown. Unknown Date: The pet owner noticed ticks on the dogs. 16 Oct 2019*: The pet owner applied 1 dose, per dog, of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, Package Unavailable), in one spot , between the shoulder blades. 17 Oct 2019*: The pet owner is still noticing ticks that are attached to each dog. The dogs have access to a fenced in grassy yard. The pet owner is seeing approximately 2 engorged ticks on each dog. No ticks have been seen in the home. The dogs have previously used FRONTLINE PLUS DOG, on unknown dates, with no reported issues. There are 2 other cats in the home that have not been treated with flea or tick treatment, and no ticks have been seen on the cats. No further medical information expected.
18-Oct-2019	UAE; 19US062164; VT; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Yellow) **Sex:** M **Sex qualifier:** - **Age:** 3.50 Year(s) **Weight:** 90 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the pet owner reported the following event for Benny, a 3.5 year old, 90 pound, intact male, Yellow Labrador Retriever. 1 Oct 2019*: The patient got their dose of FRONTLINE PLUS DOG 89-132 LBS(lot unknown, reporter refused). The owner stated she had used FRONTLINE for years, but exact dates are unknown. It is unknown as to where it was applied. 2 Oct 2019*: The owner noticed engorged ticks on the animal. The owner has not had them identified yet, but is taking them to the vet. The pet goes outside. It is unknown if the dog is having any skin issues, it is unknown if it gets bathed, and it is unknown if ticks have been seen on the owner or in the house. The ticks were removed and the animal seems to have recovered. There are more animals in the house, but the total is unknown. Further infomration is unknown as owner had to go. No further medical information expected.
18-Oct-2019	UAE; 19US062177; GA; U.S.A	**Species:** Canine **Breed:** Terrier Breeds (500 Series) **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 45 - 88 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Oct-2014*	18-Oct-2019*	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the pet owner reported the following event for Isiaha, a 7 year old, 45-88 pound, neutered male, Terrier/Lhasa Apso mix. Oct 2014*: The canine began receiving one vial of FRONTLINE PLUS DOG 45-88 LBS (FL+) (lot unknown; package unavailable) applied topically between the shoulder blades. One vial has since been applied in the same fashion monthly around the sixth, year-round. Unknown dates: Isiaha is bathed in an unknown shampoo monthly around the fifth since an unknown date. 6 Oct 2019: One vial of FL+ (S961901) (invalid lot) was applied at which time, fleas were not seen. Unknown date: An unknown duration following FL+ application, Isiaha began scratching and chewing himself which is when the reporter first began seeing an unknown volume of fleas on him. The reporter initially said Isiaha became symptomatic with the presence of fleas two weeks after the last FL+ application; however, that time of onset would be in the future and the pet owner cannot further clarify the correct time of onset. Presently, she continues to find a medium volume of fleas on the dog, but is not finding any fleas in the home. There are no other resident animals and there have been no visiting animals in the home. Isiaha goes outside in the yard for bathroom breaks. The pet owner lives in the country, but has no wooded areas close by and does not believe there is any wildlife present. No further medical information expected.

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ED_005739D_00014391-00363

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
18-Oct-2019	UAE; 19US062186; LA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 15 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Oct-2019	18-Oct-2019	2 Day(s)	D-D	Suspected Adverse Event: On 18 Oct 2019, the pet owner reported the following event for Sadie Belle, a 8 year old*, 15 pound, spayed female, Domestic Shorthair. 16 Oct 2019: One vial of FRONTLINE PLUS CATS (S40815AW) was applied to the skin between the shoulder blades. 18 Oct 2019: The pet owner noticed hair loss at application site, skin does not appear to be irritated. The pet did not present to the clinic, and the owner did not bathe the cat. The cat's current condition is ongoing. The cat has received FRONTLINE PLUS CATS monthly since an unknown date, with no other adverse events seen. There is one other cat in the household, who is also on FRONTLINE PLUS CATS, with no issues noted. No further medical information expected.
18-Oct-2019	UAE; 19US062195; IN; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 50.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	13-Jul-2019	14-Sep-2019	N/A	D-D	Suspected Adverse Event and Lack of Efficacy Claim: On 18 Oct 2019, the pet owner reported the following event for Lexi, a 50.0 pound*, 8 year old*, spayed female canine. 13 Jul 2019 to 13 Sep 2019: The pet owner applied 1 dose of FRONTLINE PLUS DOG 45-88 LBS (S61810AX), in an unknown location, to the dog. 14 Sep 2019*: The pet owner noticed that the dog began itching. 13 Oct 2019: The most recent dose was applied. 15 Oct 2019: The dog continued to itch and the pet owner found 1 flea on the dog. The dog has access to a fenced in grassy yard, that has some dirt. There are no other pets in the home and no fleas have been seen inside the home. The dog has a history of reactions to unknown flea shampoo. The dog received FRONTLINE PLUS DOG for the first time in Jul 2019. No further medical information expected.
18-Oct-2019	UAE; 19US062200; PA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 10 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Seresto Collar; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	25-Sep-2019	18-Oct-2019	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019 a pet owner reported the following event for Fireball, a 2* year old, 10* pound, neutered male Domestic Shorthair. 21 Aug 2019: The cat received 1 application of FRONTLINE PLUS CATS (S40901AW) topically between the shoulder blades in one spot for the first time. The owner is not sure if the cat had ticks prior to application but the cat was going outside. 15 Sep 2019*: The owner found 5 live attached ticks on the cat and physically removed them. 25 Sep 2019: The cat received another application of FRONTLINE. 17 Oct 2019: The cat received a Seresto collar. 18 Oct 2019: The cat received a third application of FRONTLINE. The owner saw 1 tick on the cat. The cat does go outside and they live in the county so the cat roams. There are no other pets in the home. The cat does not receive baths. No further information expected.
04-Oct-2019	UAE; 19US062223; VA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	01-Oct-2019*	02-Oct-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 04 Oct 2019, clinic staff reported the following event for an unknown signalment cat. *01 Oct 2019: The pet owner applied a dose of FRONTLINE PLUS CAT (Lot unknown/ package unavailable) topically. It is unknown if this was the first time use. *02 Oct 2019: The animal owner noted the cat having odd behavior. The pet owner looked at the package and the blister pack stated FRONTLINE PLUS DOG 45-88 LBS.

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ED_005739D_00014391-00364

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						Route: Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)					The reporter did not have inforamtion about where or when the product was purchased. She did not have specific information about the cats odd behavior. All additional information is unknown. No further information expected at this time. UPDATE 28 OCT 2019: Upon internal review, completed Misuse Type field.
18-Oct-2019	UAE; 19US062253; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 6 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Jul-2019*	18-Oct-2019*	3 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the owner reported the following event for a 6 pound canine (all other signalments unknown). 27 Jul 2019*: First dose of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) was applied topically, between the shoulder blades, by the owner. The dog had fleas prior to the application. 27 Sep 2019*: Most recent dose of FRONTLINE was applied. The owner is still seeing a small amount of fleas on the dog. The owner is not seeing fleas in the home. The dog goes outside for potty breaks in an open yard. The yard and the house have been treated with an unknown product. No further medical information expected.
18-Oct-2019	UAE; 19US062257; OR; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 8.0 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Sep-2019	19-Sep-2019	1 Day(s)	D-D	Suspected Adverse Event: On 18 Oct 2019, the pet owner reported the following event for Hannah, a 10 year old*, 5 to 8 pound*, spayed female feline. 18 Sep 2019: The pet owner applied 1 dose of FRONTLINE PLUS CATS (R41105AW), in one spot, between the shoulder blades. It is unknown if this is the very first time the cat had the product. 19 Sep 2019: The cat became lethargic and jumpy. The cat recovered 2 to 4 days later. It is unknown if the cat has had a history of reactions. The pet owner has a product quality case for the FRONTLINE PLUS CATS (See Case 19US062106). There is no further medical information expected.
18-Oct-2019	UAE; 19US062259; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Neutered **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019	17-Oct-2019	16 Day(s)	D-D	Suspected Lack Of Efficacy Claim: On 18 OCT 2019, the owner reported the following event an unknown feline, all other signalment unknown. Oct 2019: The pet owner applied 1 dose of FRONTLINE PLUS CATS (lot unknown, reporter refused) in an unknown location. 17 Oct 2019: Fleas were found on the pet while being neutered. The cat is indoor only. It is unknown if the pet had fleas prior to dosing, it is unknown how long the owner has used the product on the pet. The owner refused to answer any questions. No further medical information expected.
18-Oct-2019	UAE; 19US062263; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	04-Oct-2019*	14-Oct-2019*	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the owner reported the following event for a 10 pound canine (all other signalments unknown). Unknown date: Started on monthly doses of FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown, package unavailable) applied topically between the shoulder blades, by the owner, on a year round basis.

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ED_005739D_00014391-00365

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		Weight: 10 lbs				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					4 Oct 2019*: Most recent dose of FRONTLINE was applied. 14 Oct 2019*: The owner started seeing fleas on the dog. The owner is still seeing a small amount of fleas on the dog. The owner is not seeing fleas in the home. The dog goes outside for potty breaks in a fenced in yard. No further medical information expected.
21-Oct-2019	UAE; 19US062293; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 11.000 - 15.000 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	17-Oct-2019	19-Oct-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the pet owner reported the following event for 3 11.0 pound to 15.0 pound felines, of further unknown signalment. 16 Aug 2019, 21 Sep 2019 and 17 Oct 2019: The pet owner applied 1 dose per cat of FRONTLINE PLUS CATS (lot unknown, package unavailable), in unknown locations on the cats. 19 Oct 2019: The pet owner noticed fleas in the home and on the cats. The pet owner is currently still seeing live fleas on the cats. The cats have been treated with FRONTLINE PLUS CATS monthly since approximately 2009, with no issues. There are 2 cats that frequent the woods and 1 cat that remains strictly indoors. The pet owner is vacuuming and washing the linen the cats lay on. The cats are in good health. There are no other pets in the home. One cat has been bathed in Advantage Flea Shampoo on an unknown date. No further medical information expected.
21-Oct-2019	UAE; 19US062312; NY; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 7 - 19 lbs	6	6	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Head and Shoulders; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	14-Oct-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 October 2019, the pet owner reported the following event for 6 dogs, 7 to 19 pounds, 1 year to 11 year, mixed sexed neutered, various breeds. 21 Oct 2009*: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 5-22 LBS (F11902AL) to the skin between the shoulder blades monthly to each dog for the first time. 30 Sep 2019: The owner bathed all the dogs with Head and Shoulders shampoo. 01 Oct 2019: The owner applied a dose. 14 Oct 2019*: The owner noticed 10 live fleas on each dog for the first time. 21 Oct 2019: The owner is continuing to see about 10 live fleas on each dog. There are no other pets in the home. The dogs are outside for short periods of time. There are outdoor cats in the neighborhood. 1 dog has known flea allergies. There are no fleas seen in the home. No further medical information expected.
21-Oct-2019	UAE; 19US062322; MI; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 13 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG; **Route:** Topical / Cutaneous **Was the product used**	01-Jun-2013*	01-Jun-2013*	2 Year(s) 1 Month(s)	D-C	Suspected Adverse Event: On 21 Oct 2019 a pet owner called to report the following event in Bennie, a 13 pound, 11 year old, neutered male, Shih Tzu canine. Unknown date: The dog received an unknown amount and frequency of Sentinel for heartworm and flea prevention. 01 Jan 2011*: The dog began receiving HEARTGARD PLUS (size unknown, product unsubstantiated, lot and expiration date unknown package unavailable) by mouth monthly. 1 Apr 2011*: The dog also started receiving FRONTLINE PLUS DOG 5-22LBS (Lot and expiration date unknown, package unavailable) monthly in between the shoulder blades between the months of April and November every year. 01 Jun 2013*: The dog began having strange vocalizing episodes while he was sleeping approximately once monthly between 1am and 3am. Jun 2019*: There were 2 episodes of vocalizing at night, the owner appreciated they were becoming more frequent.

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ED_005739D_00014391-00366

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					Jul and Aug 2019*: The dog had 3 of the vocalizing episodes at night while sleeping and was having them between 1am and 3am; with these episodes he has started to urinate while having them. 14 Oct 2019*: The dog had a strange breathing episode around 6PM while he was sleeping. The owner described the breathing episode like he was hyperventilating and then started chomping his jaws. He later recovered that night. 18 Oct 2019: The most recent dose of FRONTLINE PLUS was applied to the dog. 19 Oct 2019 - 20 Oct 2019*: The dog had several more crying episodes at night and urinated while having them in the night. 2019*: The dog is being seen by a veterinarian today to be evaluated. There are no other dogs or cats in the home, they have 2 birds. The owner also reported the FRONTLINE PLUS was no longer working (see case 19US062560 for lack of efficacy claim). The pet owner is unsure if the strange vocalizing episodes are seizures or something else, he has not been diagnosed with anything. No further medical information expected.
21-Oct-2019	UAE; 19US062332; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 9 - 16 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Apr-2019	21-Oct-2019	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the owner reported the following event for 3 felines weighing 9, 11, and 16 pounds (all other signalments unknown). Unknown date: The owner started to find fleas on the cats. 2 Apr 2019*: One vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) was applied between the shoulder blades for the first time. 3 Apr 2019: The owner continued to find fleas. 2 Oct 2019: The most recent application was applied. 21 Oct 2019: The flea issue is still ongoing. The cats are strictly indoor. No further medical information is expected.
21-Oct-2019	UAE; 19US062334; KS; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 18 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Oatmeal Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Sep-2019	21-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the pet owner reported the following event for Toby, a 5 year old, 18 pound, neutered male, Shih Tzu. 20 Sep 2019: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (S61017AL). The product was applied directly on the skin between the shoulder blades. 20 Oct 2019: The most recent date of application. The pet was bathed today in an unknown oatmeal pet approved shampoo, and was completely and naturally dry before application of FRONTLINE PLUS. 21 Oct 2019: The owner noticed one flea on the dog, and the dog scratching. It is unknown what type of environment the dog frequents. The owner is not seeing any indoor flea activity. No treatments have been provided at home. The dog's current condition is ongoing. This it the only pet in the household. No further medical information expected.
21-Oct-2019	UAE; 19US062338; -; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Sentinel;	20-Oct-2019	21-Oct-2019	1 Day(s)	D-B	Suspected Adverse Event: On 21 Oct 2019, the owner reported the following event for a 2 year old (born 2 Nov 2016), 46 pound, spayed female, large crossbreed canine. May 2017*: Started on monthly doses of FRONTLINE PLUS DOG 23-44 LBS (R62420AL) topically between the shoulder blades, by the owner. The dog also started on monthly treatments of Sentinel. Nov 2017*: The dog started having tremors that lasted 10-15 seconds each. The symptoms occurred every couple of weeks but

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ED_005739D_00014391-00367

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 46 lbs				**Route:** Topical / Cutaneous **Was the product used ok?:** Yes					had at least one episode every month. Nov 2018*: The dog had a grand mal seizure. The dog's body was rigid, head was hiked back, foaming at the mouth, eyes open, and non-responsive. The seizure lasted about 90 seconds. The dog was in a postictal state for about 30 minutes to 1 hour afterwards. The dog was seen by the veterinarian and started on Phenobarbital. The seizures stopped all together. May 2019*: the owner took the dog off Phenobarbital and also stopped using FRONTLINE around the same time (the dog was still receiving monthly doses of Sentinel). 20 Oct 2019: The owner gave another dose of FRONTLINE. 21 Oct 2019: The dog had another seizure. No further medical information expected.
21-Oct-2019	UAE; 19US062351; SC; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 80.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Aug-2019	20-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: on 21 Oct 2019, the pet owner reported the following event for Tuck, a 3 year old, 80.0 pound, neutered male Golden Retriever Poodle mix. 27 Aug 2019: The pet owner applied 1 dose of FRONTLINE PLUS DOG 45-88 LBS (S61111AR), in one spot, between the shoulder blades, to the dog. 20 Sep 2019*: The pet owner noticed fleas on the dog and in the home. Unknown date: The pet owner flea bombed the house and an exterminator treated. 27 Sep 2019: The most recent treatment was applied. The pet owner is still seeing 8 to 9 live fleas on the dog. The dog has been bathed in Dawn and a flea shampoo once a week since an unknown amount of time after seeing fleas. The dog goes outside in an open field with grass for potty breaks. The dog has been treated with FRONTLINE PLUS DOG 45-88 LBS previously, monthly year round since 2018, with no issues. There are no other pets in the home. No further medical information expected.
21-Oct-2019	UAE; 19US062359; -; U.S.A	**Species:** Canine **Breed:** Bichon Frise **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 19 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	21-Oct-2019	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, a pet owner reported the following event for a 19 pound male Bichon Frise of further unknown signalment. Unknown Date: The dog started using FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable), it is unknown if the dog had fleas prior. 21 Oct 2019: The owner found a few live fleas. All further details are unknown. No further medical information expected.
21-Oct-2019	UAE; 19US062366; WI; U.S.A	**Species:** Feline **Breed:** Feline Other **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 14 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Palm Olive soap; unknown bath product; **Route:** Topical /	15-Aug-2019*	21-Oct-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the pet owner reported the following event for Mittens, a 5 year old*, 14 pound*, neutered male, English Shorthair (feline). Unknown date: The pet owners noticed an unknown volume of fleas on Mittens despite being an indoor-only cat. 15 Aug 2019*: An unknown duration after finding fleas on him, he received one vial of FRONTLINE PLUS CATS (FL+) (lot unknown; package unavailable) applied topically between the shoulder blades. At the time of application, an unknown number of fleas were on him. It's unknown if Mittens has previously received FL+; however, the two subsequent dates of application are as follows: 15 Sep 2019*, and 15 Oct 2019*.

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ED_005739D_00014391-00368

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** Yes					Unknown dates: An unknown duration following initial FL+ application, the reporter continued to see an unknown number of fleas on Mittens. An unknown time after product application, the reporter's wife began combing an unknown number of fleas off using a flea comb dipped in Palm Olive soap. An unknown duration thereafter, either after the first or second FL+ application, the reporter's wife then bathed the cat with an unknown bath product to rid him of the increasing number of fleas present. Presently, the reporter is finding an even larger number of fleas on Mittens than when FL+ was first applied and fleas are being found in the home and biting the pet owners. There have been no visiting animals and there are no resident animals in the home. No further medical information expected.
21-Oct-2019	UAE; 19US062367; NC; U.S.A	**Species:** Canine **Breed:** Weimaraner **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 66 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Maxi Otic; Benadryl 25 mg; Prednisone 20 mg; doxycycline 100mg; Unknown shampoo; **Route:** unknown **Was the product used ok?:** Unknown to Company	09-Oct-2019*	11-Oct-2019	2 Day(s)	D-C	Suspected Adverse Event: On 21 Oct 2019 the owner reported the following event for Merlin, a 4 year old*, 66 pound*, neutered male, Weimeraner. 5 Oct 2019 through 11 Oct 2019: The pet was boarded at the veterinarian clinic. The pet was bathed with an unknown shampoo on an unknown date. A unknown person applied an unknown amount of FRONTLINE (lot unknown,package unavailable, product unsubstantiated) to an unknown location by an unknown route on an unknown date. The pet was also being treated for a ear infection with Maxi Otic. 11 Oct 2019: The owner picked up the pet from boarding. On further inspection the pet owner noticed the pet had blood in his ears and was covered in hives. 12 Oct 2019: The owner contacted the veterinarians office due to the hives, per the direction of the veterinarian the pet was given two 25 mg tablets of Benadryl and one tablet of 20 mg prednisone. The pet seemed to get better after medication was given. 13 Oct 2019: The pet continued to look better, the owner did not administer any medications. 14 Oct 2019:The pet started to look and act depressed. The pet appeared to have red patches on his skin. The owner gave two 25 mg Benadryl and one 20mg Prednisone 15 Oct 2019: The pet seemed to get better and then declined as the day went on. The pets ears started to bleed. The owner washed the pets ears with an unknown ear wash. 16 Oct 2019: The pet was given 20mg of prednisone. 17 Oct 2019: The pet began to cough. The pet was not presented to the veterinarian. 19 Oct 2019: The pet was presented to the veterinarian. The pet had a fever of 105.0*F and was continuing to cough. The pet was prescribed 100mg doxycycline twice daily for 10 days. 21 Oct 2019: The pet continues to cough and have green discharge from eyes. It is unknown if the pet has a fever as the owner does not have a thermometer. The pet has swollen glands on unspecified parts of the pets body. The pet has a hunched posture and gait as if he is painful. The pet lives in a
21-Oct-2019	UAE; 19US062374; -; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** -	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products	10-Oct-2019	21-Oct-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the pet owner reported the following event for a 2 month old* mix breed male intacted canine of unknown weight. 10 Oct 2019: The foster applied FRONTLINE SPRAY (Lot unknown) (package unavailable) by an unknown route and an unknown dose. 21 Oct 2019: The new owner noticed the pet scratching and seeing

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ED_005739D_00014391-00369

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 2.00 Month(s) **Weight:** Unknown				**Route:** unknown **Was the product used ok?:** Unknown to Company					a very small amount of flea dirt. No live fleas have been seen. The owner has not been noticing fleas off of the pet inside the home. The pet has not been bathed. It is unknown if the pet has any skin issues. The yard is fenced with grass and wildlife present. The pet has not presented to the veterinarian. The pet is indoor/outdoor. There is a total of 1 canine in the household. No further medical information expected.
21-Oct-2019	UAE; 19US062389; WA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 50 lbs	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Jan-2014*	01-Jun-2014*	5 Month(s)	D-A	Suspected Adverse Event: On 21 Oct 2019, the pet owner reported the following event for a 50 pound* dog with otherwise unknown signalment. The caller was calling to check on expiration for leftover product. 2014*: The dog began receiving FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown, package unavailable) monthly. Unknown date (approx.1 Jun 2014 for reporting purposes): The dog passed away of unknown causes. No other information could be provided. No more information expected.
21-Oct-2019	UAE; 19US062390; NJ; U.S.A	**Species:** Canine **Breed:** Retriever (Chesapeake Bay) **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 123 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Ketochlor Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Oct-2019	10-Oct-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the pet owner reported the following event for Buoy, an 11 years old, 123 pound, mal neutered Retriever (Chesapeake Bay). 2008*: The pet began receiving FRONTLINE PLUS DOG (Lot unknown) (package unavailable), applied 1 vial topically between the shoulder blades monthly. 6 Oct 2019: The most recent dose is applied, FRONTLINE PLUS DOG 89-132 LBS (Lot unknown) (package unavailable). 10 Oct 2019: The owner began noticing a small amount of fleas on the pet. Fleas have been seen continuously since 10 Oct 2019. The owner has not been noticing fleas off of the pet inside the home . The pet is bathed occasionally with Ketochlor and does allergies that cause some skin issues. The yard is fenced with grass, lakefront and wildlife are present. The pet has not presented to the veterinarian. The pet is indoor/outdoor. There a total of 1 canine and 2 felines in the household. One of the cats in indoor only and is treated with Advantage and fleas are not being seen on this pet. The other cat is outdoor only and not treated. It is unknown if there are fleas on this cat. No further medical information expected.
21-Oct-2019	UAE; 19US062392; CA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 5.0 - 17.0 lbs*	7	7	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown pet approved shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-May-2019*	29-Aug-2019*	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the animal owner reported the following event for seven canines, 8.0 to 15.0 years old*, 5.0 to 17.0 pounds*, otherwise unknown signalment. May 2019* through 05 Oct 2019: The owner had not noticed fleas on the canines. The owner had not noticed fleas off of the canines inside of the home. They received FRONTLINE PLUS DOG 5-22 LBS (S62507AX) one dose per canine applied topically between the shoulders monthly for the first time this year. 29 Aug 2019*: The owner noticed a small amount of fleas on the canines. The owner has been noticing fleas off of the canines inside of the household. The canines frequent the stone covered property. They have not presented to the veterinary clinic. No treatments have been performed. Sep 2019*: The owner took the canines camping where they laid in a dirt environment routinely.

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ED_005739D_00014391-00370

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											05 Oct 2019: The owner continues to see fleas and the canines and within the household. The owner bathed the canines in an unknown pet approved shampoo. The owner applied the most recent application once the canines were naturally dry. 21 Oct 2019: The owner is continuing to see fleas on the canines and within the household. The owner does bathe the canines approximately once a month with unknown pet approved shampoo. There are no other pets in the household. No further medical information expected.
21-Oct-2019	UAE; 19US062421; OH; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 13 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Oct-2019	16-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 21 Oct 2019, the owner reported the following event for Bella, an approx. 5 year old, approx. 13 pound, spayed female, small crossbreed canine. 16 Oct 2019: First dose of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable) was applied topically between the shoulder blades, by the owner. Later that day, the skin at the application site was red. Unknown date: The owner treated the dog with Benadryl. The symptoms are ongoing. The dog was not seen by a veterinarian. No further medical information expected.
21-Oct-2019	UAE; 19US062440; OH; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	08-Oct-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 21 Oct 2019, a pet owner reported the following event for Romeo, a 7 year old*, 10 pound, neutered male Domestic Shorthair. 2016*: The cat began receiving monthly year round applications of FRONTLINE PLUS CATS (Lot Unknown, Package Unavailable) topically between the shoulder blades in one spot. 1 Oct 2019: The cat received 1 application of FRONTLINE PLUS CATS (S40601AX). 8 Oct 2019*: The owner noticed 2-3 live fleas on the cat and has continued to see fleas daily. 21 Oct 2019*: The owner felt a bump on the cat where the FRONTLINE had been applied. There are no other pets in the home. The cat does go outside and roams around. There is no flea activity inside the home. The cat does not receive baths. No further information expected.
21-Oct-2019	UAE; 19US062444; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 8 - 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Sep-2019*	17-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the owner reported the following event for an approx. 8-10 pound feline (all other signalments unknown). Mar 2019*: The owner started treatment with FRONTLINE PLUS CATS (lot unknown, package unavailable) applied topically, between the shoulder blades, by the owner, every 6 weeks. Aug 2019*: The owner started applying the FRONTLINE every 3-4 weeks. 16 Sep 2019*: Another dose of FRONTLINE was applied. Unknown date: The owner started seeing fleas in the cat. 7 Oct 2019*: Most recent dose of FRONTLINE was applied. The owner is still seeing a small amount of fleas on the cat. The cat goes outside once a day in a fenced in yard with trees and bushes. No further medical information expected.
21-Oct-2019	UAE; 19US062455; -; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20	1	1	0	**Product used:** FIPRONIL 10%/S	27-Sep-2019	07-Oct-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the owner reported the following event for 50 pound, spayed female, canine (all other signalments unknown).

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ED_005739D_00014391-00371

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** - **Weight:** 50 lbs				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					27 Sept 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S62408AX) was applied between the shoulder blades. 7 Oct 2019: The owner noticed fleas on the dog. 21 Oct 2019: The issue is still ongoing. The dog has received the product monthly since 27 Jul 2019 with no issue. there is 1 other dog and 2 cats in the home being treated with another product and having no issue. No further medical information is expected.
21-Oct-2019	UAE; 19US062483; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Oct-2019	21-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 21 Oct 2019, the pet owner reported the following event for a feline of unknown signalment. 21 Oct 2019: The pet received FRONTLINE PLUS CAT (lot unknown) (package unavailable), applied topically between the shoulder blades for the first time. The pet licked the product and began hypersalivating. The pet recovered shortly after. No further medical information expected.
21-Oct-2019	UAE; 19US062494; -; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 62 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Oct-2019	21-Oct-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the pet owner reported the following event for Peka, 62 pounds, 11 year, spayed female, Labrador Retriever. 11 Mar 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS 45-88 LBS (S60502AX) to the skin between the shoulder blades for the first time monthly of the season. 11 Oct 2019: The owner applied a dose. 20 Oct 2019: The owner took the dog hiking in the a wooded area. 21 Oct 2019: The owner found an attached dead American Dog Tick for the first time that was removed by the veterinarian. There is one other dog in the home that experienced an adverse reaction to FRONTLINE PLUS (19US062512) and one cat. No further medical information expected.
21-Oct-2019	UAE; 19US062497; PA; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** - **Age:** 5.00 Month(s) **Weight:** 38.9 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	18-Oct-2019	18-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 21 Oct 2019 the veterinarian reported the following event for Dino a 5 month old (1 Apr 2019), 38.9 pound, intact male, Golden Retriever. 18 Sep 2019*: The owner applied one vial of FRONTLINE PLUS DOG 23- 44 LBS (lot unknown, package unavailable) topically down the back for the first time. At an unknown time after the product was applied, the pet became agitated and started rubbing his back. The pet recovered with no treatment at an unknown time. 18 Oct 2019: The owner applied FRONTLINE PLUS to the pet. At an unknown time after the product was applied the pet became agitated and started rubbing his back. The pet recovered at an unknown time later that day with no treatments. The pet is in good health and it is unknown if he has had previous reactions to medications. The veterinarian feels this is the pet and not the medication. The FRONTLINE PLUS was not prescribed by the veterinarian. No further medical information expected.
21-Oct-2019	UAE; 19US062508;	**Species:** Canine **Breed:** Retriever	1	1	0	**Product used:** FIPRONIL	18-Oct-2019	21-Oct-2019	3 Day(s)	D-B	Suspected Adverse Event: On 21 Oct 2019 a pet owner report the following event in Penny, a 4 year old (24 Oct 2014), 70 pound*,

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ED_005739D_00014391-00372

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	MN; U.S.A	Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 70 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					spayed female, Labrador Retriever canine. 1 Apr 2019*: The dog started to recieve one dose of NEXGARD (136MCG)(Lot and expiration date unknown, package unavailable) by mouth monthly with the last dose given on 1 Sep 2019*. 18 Oct 2019: The pet owner applied FRONTLINE PLUS 45-88LBS (R62001AR) in between the shoulder blades for the first time this year. 21 Oct 2019: The dog started to become ataxic. She is having a hard time getting up and walking. It seems like her limbs are weak. Her eyes are droopy. The dog has had a previous episode of symptoms like this in 2018 (see case 19US062541) that she recovered from. The dog is still eating, drinking, urinating, and defecating normally. The dog has not been seen by a veterinarian yet. No further information at this time. UPDATE 23 Oct 2019: Per the owner, the dog is doing the same and she is still able to walk, urinate, and defecate on her own. She is eating and drinking normally and has a bright, alert, and responsive demeanor. No further medical information is expected.
21-Oct-2019	UAE; 19US062512; -; U.S.A	**Species:** Canine **Breed:** Vizla **Sex:** M **Sex qualifier:** - **Age:** 17.00 Month(s) **Weight:** 44.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Aug-2019*	12-Aug-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 21 Oct 2019, the pet owner reported the following event for Blue, 44 pounds, 17 month, intact male, Vizla. 11 Aug 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 23-44 LBS (lot unknown/ package unavailable) to the skin between the shoulder blades. It is unknown if this was the first application. 12 Aug 2019*: The dog developed irritated bumps all over his body. It was most noticeable on the sides and back. 23 Sep 2019*: The pet recovered, no treatment had been given. There is one other dog in the home on FRONTLINE PLUS (19US062494) and one cat. The dog goes outside into wooded areas to hike. No further medical information expected.
21-Oct-2019	UAE; 19US062518; OH; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Oct-2019*	21-Oct-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the pet owner reported the following event for 3 cats, with unknown signalment. March 2019*: The cats began receiving FRONTLINE PLUS CATS (lot unknown, package unavailable) monthly. The product was applied directly on the skin between the shoulder blades. 7 Oct 2019*: The most recent date of application. 21 Oct 2019: The owner noticed the cats scratching and the veterinarian found several fleas on one of the cats. The cats are indoor only. Treatments have been initiated on one cat with an unknown injection and Advantix. The cats' current conditions are ongoing. These are the only pets in the household. No further medical information expected.
21-Oct-2019	UAE; 19US062536; FL; U.S.A	**Species:** Feline **Breed:** Siamese **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 12 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	01-Oct-2019	14-Oct-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the pet owner reported the following event for Simon, a 9 year old, 12 pound, neutered male, Siamese. 1 Sep 2019*: The cat began receiving FRONTLINE PLUS CATS (S40606). The product was applied directly on the skin between the shoulder blades. 1 Oct 2019: The most recent date of application. 14 Oct 2019*: The owner has noticed two ticks on the cat. It is unknown what type of tick species. The cat did have access to the outdoors, with trees and brush on the property. The cat is currently indoor only. No treatments have been provided at home. The cat's current condition is ongoing.

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ED_005739D_00014391-00373

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					This the only pet in the household. No further medical information expected.
21-Oct-2019	UAE; 19US062541; MN; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 70 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Aug-2018*	05-Aug-2018*	4 Day(s)	D-B	Suspected Adverse Event: On 21 Oct 2019 a pet owner report the following event in Penny, a 3 year old (24 Oct 2014), 70 pound*, spayed female, Labrador Retriever canine. 1 Apr 2018*: The dog started to receive one dose of NEXGARD (136MCG)(Lot and expiration date unknown, package unavailable) by mouth monthly with the last dose given on 1 Jun 2018*. 1 Jul 2018*: The pet owner applied FRONTLINE PLUS 45-88LBS (R62001AR) in between the shoulder blades for the first time this year. Another dose was applied 1 Aug 2018*. 5 Aug 2019*: The dog started to become ataxic. She had a hard time getting up and walking. It seemed like she had become paralyzed. She continued eating, drinking, urinating, and defecating. 6 Aug 2018*: The dog was seen by a veterinarian. They referred her to a specialist. The dog was later seen at the specialist. They declined a MRI. A few other diagnostics were done (unknown what), but no conclusive results were found. The dog was not treated at that time. She was carried outside to go to the bathroom. The owner reports the dog's mentation was bright alert and responsive during this period. 10 Aug 2018*: The dog began to recover. She slowly regained movement in her front legs, and then her back legs. 20 Aug 2018*: The dog fully recovered. No further medical information expected. UPDATE 30 Oct 2019: See case 19US062508 for a subsequent case.
21-Oct-2019	UAE; 19US062546; AR; U.S.A	**Species:** Canine **Breed:** Terrier Breeds (500 Series) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 10.5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Sep-2019	21-Oct-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the pet owner reported the following event for Holly, 10.5 pounds, 3 year*, spayed female, Terrier mix. 27 Jun 2019: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 5-22 LBS (S62106AL) to the skin between the shoulder blades monthly for the first time after seeing 18 live fleas on the pet. 29 Sep 2019: The owner applied a dose. 13 Oct 2019: The owner bathed the dog with Hertz Flea Shampoo and applied Happy Jack Flea Killer. 21 Oct 2019: The owner reports continuing to see 18 to 24 live fleas on the pet daily. There are no other pets in the home. There are no prior skin conditions. The dog goes outside in the yard for short periods of time. The owner had the yard treated with an unknown product. Fleas are not being seen in the home. The owner mentioned the possibility of raccoons going through her yard. No further medical information expected.
21-Oct-2019	UAE; 19US062551; NC; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 17.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	06-Oct-2019	10-Oct-2019*	4 Day(s)	D-C	Suspected Adverse Event: On 21 Oct 2019, the pet owner reported the following event for Tuffy, a 3 year old, 17.0 pound, neutered male feline. 6 Oct 2019: The pet owner applied 1 dose of FRONTLINE PLUS CATS (S40606AW), in a spot an inch and a half caudal to the shoulder blades. 10 Oct 2019*: Approximately 4 to 5 days later, the pet owner noticed hair loss at the application site. The next day, a small sore had developed. Approximately a week later, the cat experienced loose stool.

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						Was the product used ok?: No (Treatment / vaccination program not respected)					20 Oct 2019: The cat presented to the veterinary clinic and was treated with an unknown steroid injection and an unknown antibiotic injection. The cat is currently not recovered. The cat was in good health and was not receiving any other medications. There is no history of reactions. No further medical information expected.
21-Oct-2019	UAE; 19US062558; IL; U.S.A	**Species:** Canine **Breed:** Siberian Husky **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 41.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Feb-2012*	10-Oct-2019*	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the animal owner reported the following event for Regan, a 8.0 year old*, 41.0 pound, spayed female Siberian Husky Border Collie Mix. 2012* through 15 Sep 2019: The owner had not noticed fleas on the canine. The owner had not noticed fleas off of the canine inside of the home. She received FRONTLINE PLUS DOG 23-44 LBS (S62308AW) one dose per canine applied topically between the shoulders. 10 Oct 2019*: The owner noticed a moderate amount of fleas on the canine. The owner has not been noticing fleas off of the canine inside of the household. The canine does frequent the grass covered property. The owner notes there is urban wildlife present. She presented to the veterinary clinic. Treatment was initiated with NEXGARD (unsubstantiated) (lot and expiration unknown). The owner does bathe the canine approximately twice a year with an unknown pet approved shampoo. There are no other pets in the household. No further medical information expected.
21-Oct-2019	UAE; 19US062560; MI; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 13 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Apr-2019*	09-Sep-2019*	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019 a pet owner called to report the following event in Bennie, a 13 pound, 11 year old, neutered male, Shih Tzu canine. 1 Apr 2019*: The dog started receiving FRONTLINE PLUS DOG 5-22LBS (Lot and expiration date unknown, package unavailable) monthly in between the shoulder blades between the months of April and November. 18 Aug 2019*: A dose of FRONTLINE PLUS was applied. 9 Sep 2019*: The owner started to see fleas on the dog, at least one per day. They are not seeing them in the home. 18 Oct 2019: The most recent dose of FRONTLINE PLUS was applied to the dog. 21 Oct 2019: The pet owner continues to see fleas, they have not stopped seeing fleas since 9 Sep 2019*: The dog is being seen by a veterinarian today to be evaluated. There are no other dogs or cats in the home, they have 2 birds. The dog is leash walked daily and has access to a fenced yard. The pet owner is unsure if there is urban wildlife in the area. The dog is having neurological episodes and the owner suspects FRONTLINE PLUS (see case 19US062322 for the adverse reaction). No further medical information expected.
21-Oct-2019	UAE; 19US062562; IN; U.S.A	**Species:** Feline **Breed:** Norwegian Forest Cat **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 5 lbs	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	01-Jan-2017*	11-Oct-2019*	5 Week(s) 5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019 the owner reported the following issue for Fuzzy, a 2 year old*, 5 pound*, unknown male, Norwegian Forest Cat. 1 Jan 2017* through 1 Sep 2019*: The owner applies one vial of FRONTLINE PLUS CATS (L40412AW) topically between the shoulder blades monthly, year round. 11 Oct 2019*: The owner noticed 2 fleas* on the pet. 17 Oct 2019*: The owner applied FRONTLINE PLUS to the pet. The pet has access outside to a grass yard, where urban wildlife and stray cats are seen. The pet also has access to a garage in the home. There are 2 other cats in the home being treated with

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ED_005739D_00014391-00375

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: No (Treatment / vaccination program not respected)					FRONTLINE PLUS, no fleas are seen on these pets. The pet is not bathed. No fleas are seen in the home. No further medical information expected.
21-Oct-2019	UAE; 19US062566; MI; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	22-Sep-2019	22-Sep-2019	0 Day(s)	D-A	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 21 Oct 2019, the pet owner reported the following event for Emma, a older female feline of unknown signalment. 22 Sep 2019: The owner noticed a small amount of fleas on the pet. The owner bought a 6 pack and applied FRONTLINE PLUS CAT (R40312AW), 1 vial topically between the shoulder blades for the first time. Sep 2019*: The pet was bathed twice in Dawn dish soap. 19 Oct 2019: The pet passed away. It is unknown if the death was related to the fleas Fleas have been seen continuously since 22 Sep 2019. The owner has not been noticing fleas off of the pet inside the home . It is unknown if the pet had any skin issues. The yard is fenced with grass. The pet has not presented to the veterinarian. The pet is indoor only. There a total of 3 canines, a litter of 4 week old puppies and 1 feline in the household. The other feline is treated with FRONTLINE PLUS CAT, see case 19US062561. The other pets are treated with FRONTLINE PLUS DOG and fleas are being seen on these pets. See cases 19US062561. No further medical information expected.
21-Oct-2019	UAE; 19US062568; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	18-Oct-2019	18-Oct-2019*	0 Day(s)	D-C	Suspected Adverse Event: On 21 Oct 2019, the pet owner reported the following event for a female feline of further unknown signalment. 18 Oct 2019: A friend applied an unknown amount of unknown FRONTLINE PLUS CATS (lot unknown; package unavailable) (product unsubstantiated) topically in an unknown location. An unknown duration following product application, the reporter came home and found the cat was not acting like herself. She was hiding and inappetent. 20 Oct 2019: The feline began eating again. 21 Oct 2019: The feline is eating, but still doesn't have a normal appetite. She is also laying around outside which is atypical behavior as she is normally running around and hunting. Otherwise, she seems to be in good health. It's unknown if the feline has previously received unknown FRONTLINE PLUS CATS. No further medical information expected.
21-Oct-2019	UAE; 19US062571; MI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 25.000 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Seresto Collar; **Route:** Topical / Cutaneous **Was the product used**	22-Aug-2019	22-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the pet owner reported the following event for Gracie a 6 year old 25 pound female spayed canine of unknown breed. 22 Sep 2019: The owner noticed a small amount of fleas on the pet. The owner bought a 3 pack and applied FRONTLINE PLUS DOG 23-44 LBS (S61009AL), 1 vial per animal topically between the shoulder blades monthly. The dogs are treated seasonally from April through December. Sep 2019*: The pets were bathed twice in Dawn dish soap. Fleas have been seen continuously since 22 Sep 2019. The owner has not been noticing fleas off of the pet inside the home . It is unknown if the pets have any skin issues. The yard is fenced with grass. The pets has not presented to the veterinarian. The pets are

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ED_005739D_00014391-00376

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					indoor/outdoor. The pets also wear seresto collars. There a total of 3 canines, a litter of 4 week old puppies and 1 feline in the household. The feline is treated with FRONTLINE PLUS CAT, see case 19US062561. There was another cat that passed away on 19 Oct 2019, see case 19US062566. The other dog are treated with FRONTLINE PLUS DOG 89-132 LBS and fleas are being seen on these pets. See case 19US062576 and 19US063438. The puppies are not being treated and not live fleas have been seen. No further medical information expected.
21-Oct-2019	UAE; 19US062574; IA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 20.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Oct-2017*	14-Oct-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the reported the following event for George, a 4 year old*, 20.0 pound*, neutered male Domestic Shorthair 2017* through 12 Oct 2019: The owner had not noticed fleas on the feline. The owner had not noticed fleas off of the feline inside of the home. He received FRONTLINE PLUS CATS (P40203BW) one dose per feline applied topically between the shoulders monthly year round. 14 Oct 2019*: The owner noticed a small amount of fleas on the feline. The owner has not been noticing fleas off of the feline inside of the household. The feline does frequent the grass covered property and porch on leash. She has presented to the veterinary clinic. No treatments have been performed. The owner does bathe the feline at unknown intervals with the most recent bath on 14 Oct 2019* with an unknown pet approved shampoo. There are no other pets in the household. No further medical information expected.
21-Oct-2019	UAE; 19US062575; NJ; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 75 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Sep-2019	21-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019 the pet owner reported the following event for a 75 pound, female canine of unknown further signalment. 1 Feb 2019*: Started on FRONTLINE PLUS DOG 45-88 LBS (lot number unknown, package unavailable), 1 vial topically, in between the shoulder blades, once monthly. 15 Sep 2019: The pet owner applied one dose. 21 Sep 2019: The pet owner began seeing a large amount of fleas periodically on the canine. 23 Sep 2019*: The pet owner bathed with an unknown brand of flea shampoo. 15 Oct 2019: The most recent dose was applied. 21 Oct 2019: Currently, the pet owner is seeing a large amount of fleas on the canine but none inside the home. The canine spends the majority of the time outside the home with access to a lawn and wooded areas. There are no other pets inside the home. No further medical information is expected.
21-Oct-2019	UAE; 19US062578; CA; U.S.A	**Species:** Canine **Breed:** American Staffordshire Terrier **Sex:** M **Sex qualifier:** - **Age:** 1.50 Year(s) **Weight:** 95 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jun-2019*	01-Aug-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, a pet owner reported the following event for Thomas, a 1.5 year old, 95 pound, intact male American Staffordshire. 1 Jun 2019: The dog started FRONTLINE PLUS DOG 89-132 LBS (lot unknown, package unavailable) 1 vial topically between the shoulder blades for the first time. It is unknown if fleas were present. 1 Jul 2019 and 1 Aug 2019: The most recent dose was applied. 1 Aug 2019: The owner is seeing fleas. All further details are unknown. No further medical information expected.

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ED_005739D_00014391-00377

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
22-Oct-2019	UAE; 19US062598; PA; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 Month(s) **Weight:** 35 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Aug-2019	22-Oct-2019*	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the owner reported the following event for Louis, a 14 month old, male , neutered, 35 pound, Australian Shepard and Shih Tzu Mix. 10 Sep 2019: One vial of the FRONTLINE PLUS DOG 23-44 LBS (S60713AX) applied in between the shoulder blades by the owner.1 tick was found on the pet. 10 Oct 2019: One vial of the FRONTLINE PLUS DOG 23-44 LBS (S60713AX) applied in between the shoulder blades by the owner. Unknown Date: 5 engorged ticks were found on the pet. There are no visiting pets within the home and no wildlife has been seen in the area. No indoor fleas were seen. The dog has access to an open area with an invisible fence. No further medical information is expected.
07-Oct-2019	UAE; 19US062609; OH; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 12 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)	01-Sep-2019*	01-Sep-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 7 Oct 2019 the owner reported the following event for Fred, a 5 year old*, 12 pound*, neutered male, Domestic Shorthair. 1 Sep 2019*: The pet owner applied one vial of FRONTLINE PLUS DOG 45-88 LBS (R41105AW) topically between the shoulder blades , that was contained in a FRONTLINE PLUS CATS box (see case 19US059657). A few hours* after application the cat began to drool and act agitated. The cat recovered on an unknown date. It is not known if the cat received any treatments. The health of the pet prior to application is unknown. No further medical information expected. UPDATE 23 Oct 2019: After Quality department review, it was confirmed that reported product quality issue is not a product defect.
22-Oct-2019	UAE; 19US062611; NY; U.S.A	**Species:** Canine **Breed:** Rottweiler **Sex:** M **Sex qualifier:** - **Age:** 6.00 Week(s) **Weight:** 23 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	13-Sep-2019	14-Sep-2019*	N/A	D-D	Suspected Adverse event Claim: On 22 Oct 2019, the pet owner reported the following event for Ozzie, an 6 week old (DOB: 2 Aug 2019), 23 pound, male intacted Rottweiler. 13 Sep 2019: The owner bought a 3 pack and applied FRONTLINE PLUS DOG 23-44 (S61009AL), 1 vial topically between the shoulder blades for the first. 14 Sep 2019*: Owner noticed the pet inching and scratching more than usual. No live fleas or flea dirt have been seen. 13 Oct 2019: The most recent dose is applied. 15 Oct 2019: The pet was bathed with puppy shampoo. 22 Oct 2019: The pet has continued to scratch during this time. The pet does not have any skin issues besides the scratching. The yard is fenced with grass. The pet has not presented to the veterinarian. The pet is indoor/outdoor. There a total of 1 canine in the household. No further medical information expected. UPDATE 25 Oct 2019: The pet reacted to doses from 2 different lot numbers. The additional lot number is S62307AW.
22-Oct-2019	UAE; 19US062649; NY; U.S.A	**Species:** Feline **Breed:** Maine Coon Cat **Sex:** F **Sex qualifier:** Neutered **Age:** 18.00 Year(s) **Weight:** 7 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products	08-May-2019*	11-Oct-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the pet owner reported the following event for Maddie, a 18 year old, 7 pound, spayed female, Maine Coon Cat. 8 Oct 2019: The patient got their dose of FRONTLINE PLUS CAT (M40906AW). The animal has gotten a dose once every month since May 2019*. The owner purchased a 3 pack this past purchase, and the animal has used FRONTLINE whole life during the summer seasons ending in winter. It was applied between the

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ED_005739D_00014391-00378

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** Yes					shoulder blades. 11 Oct 2019: The owner noticed ticks on the cat. The ticks were not identified, the owner removed them. The pet goes outside. The pet is showing no skin issues. The owner does not bathe the pet. The owner is not sure if they are in the house, she has not seen them. However she did see one on herself. The patient's current condition is recovered Maddie is the only feline in the household. The owner stated this happend last year around the same time, see case 19US064083. No further medical information expected.
22-Oct-2019	UAE; 19US062676; NY; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Yellow) **Sex:** F **Sex qualifier:** - **Age:** 10.00 Week(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Oct-2019	20-Oct-2019	3 Day(s)	D-D	Suspected Adverse Event: On 22 Oct 2019 the owner reported the following event for Gigi, a 10 week old*, 10 pound*, intact female, Yellow Labrador Retriever. 17 Oct 2019: The owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS (S63009BL) topically between the shoulder blades for the first time. 20 Oct 2019: The pet started to be itchy and whine. The pet seems very uncomfortable. 22 Oct 2019: the pet continues to be itchy and uncomfortable. The issue is ongoing and no treatments have been given. The owner plans to bring the pet to the veterinarian for treatment. The pet was in good health and has no history of reactions. The owner also applied the product to a family members dog from the same lot, see case 19US062679. No further medical information expected.
22-Oct-2019	UAE; 19US062679; NY; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Yellow) **Sex:** F **Sex qualifier:** - **Age:** 10.00 Week(s) **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Sep-2019	21-Oct-2019	4 Week(s) 5 Day(s)	D-D	Suspected Adverse Event: On 22 Oct 2019 a family member reported the following event for Luna, a 10 week old*, 15 pound*, intact female, Yellow Labrador Retriever. 18 Oct 2019: The family member applied one vial of FRONTLINE PLUS DOG 5-22 LBS (S63009BL) topically between the shoulder blades for the first time. 21 Oct 2019: The pet started to be itchy and whine. The pet seems very uncomfortable. The issue is ongoing and no treatments have been given. The owner plans to bring the pet to the veterinarian for treatment. The pet was in good health and has no history of reactions. The reporter also applied the product to her personal dog from the same lot, see case 19US062676. No further medical information expected.
22-Oct-2019	UAE; 19US062681; MI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 69.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Aug-2018*	22-Oct-2019*	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the pet owner reported the following event for Mystic, a 3 year old, 69.0 pound, spayed female canine. 12 Aug 2019 to 12 Oct 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (S62111AL), in one spot, between the shoulder blades. Unknown date: The pet owner noticed the dog biting and itching, but is unsure when it started. 22 Oct 2019: The dog presented to the veterinary clinic for a yearly appointment and the veterinarian noticed 1 live flea and 2 dead fleas. The dog was treated with NEXGARD (unsubstantiated). The dog has access to a fenced in yard that has grass and bushes. Rabbits and squirrels frequent the yard. No fleas have been seen in the home. The dog has received FRONTLINE PLUS DOG 45-88 LBS monthly since 2018, with no issues. It is unknown if other pets are in the home. No further medical information expected.

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ED_005739D_00014391-00379

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
22-Oct-2019	UAE; 19US062689; NY; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 9 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Oct-2019	20-Oct-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the pet owner reported the following event for Molly a 8 year old, 9 pound spayed female Domestic shorthair. Unknown: Pet has received FRONTLINE PLUS CAT and other flea and tick products in the past on unknown dates. 14 Oct 2019: The pet began receiving FRONTLINE PLUS CAT (T40109AW), applied 1 vial topically between the shoulder blades for the first time this season. 20 Oct 2019: The owner found and removed an attached, engorged alive tick. The environment is unknown. The tick species in unknown. No further medical information expected.
22-Oct-2019	UAE; 19US062693; KY; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Advantage II; Dawn dish detergent; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Aug-2019*	15-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the pet owner reported the following event for two felines of unknown signalment. 2019 (unknown dates): Over the summer, the reporter found both cats outside at which time, they had a large volume of fleas on them. An unknown time thereafter, she bathed them in Dawn dish soap to remove all of the fleas. 14 Jun 2019*: An unknown duration after first noticing fleas, the reporter administered unknown Advantage II to each cat for the treatment of fleas. An unknown number of fleas were present on each cat when the product was administered. Unknown date: An unknown duration following Advantage II administration, the reporter continued to find an unknown volume of fleas on each cat, particularly when she combed them. 14 Jul 2019*: She administered a second unknown dose of Advantage II to each feline at which time, an unknown volume of fleas were observed on each cat. Unknown date: An unknown duration following Advantage II administration, the reporter continued to find an unknown volume of fleas on each cat. She also noticed fleas when she was combing each feline. 14 Aug 2019*: Each cat began receiving one vial of FRONTLINE PLUS CATS (FL+) (S41307AW) applied topically between the shoulder blades. At the times of application, an unknown numbers of fleas were seen on each cat. Neither feline has previously received FL+. All subsequent FL+ applications are applied in the same manner. Unknown date: An unknown duration following FL+ application, the reporter noticed an unknown number of fleas on each cat. Some of the fleas were hyperactive and others seemed sluggish. 14 Sep 2019*: Each cat received a second vial of FL+ at which time, an unknown number of fleas were present. Unknown date: Like before, the reporter noticed an unknown number of slow moving fleas and an unknown number of hyperactive fleas on each feline and unknown duration after FL+ was applied. 14 Oct 2019: An unknown number of fleas were seen on
22-Oct-2019	UAE; 19US062717; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	22-Jul-2019	23-Aug-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the owner reported the following event for a canine weighing 35 pound (all other signalments unknown). 22 Jul 2019:The dog began receiving monthly doses of FRONTLINE PLUS DOG 23-44 LBS (R62540AL) and one vial was applied between the shoulder blades. 22 Aug 2019: Another vial was applied.

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ED_005739D_00014391-00380

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 35 lbs				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					23 Aug 2019*: The owner started to notice fleas for the first time and the dog scratching her fur out. 21 Oct 2019: The most recent vial was applied. No fleas were noted in the home. 22 Oct 2019: The issue is still ongoing. The dog has access to open yard. No other pets in home. No further medical information is expected.
22-Oct-2019	UAE; 19US062719; WI; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** X **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 8 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Sep-2019	20-Oct-2019*	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, a pet owner reported the following event for 2, 4 to 6 year old, 8* pound, mixed sex neutered Domestic Medium Hair cats. 9 Sep 2019: The cats each received 1 application of FRONTLINE PLUS CATS (S41103AW) topically between the shoulder blades in one spot for the first time. The cats had a small amount of fleas and were scratching prior to application. 9 Oct 2019: The cats received a second application. The owner noticed that they were scratching and saw an unknown amount of live fleas on them. 20 Oct 2019*: The owner noticed that the cats had tapeworms. Prior to the FRONTLINE, the cats were bathed in Dawn detergent and wore a flea collar on unknown dates. The cats are indoor only but the grandson did accidentally let one of the cats outside. There is no flea activity inside the home. The owner has been spraying inside the home with an unknown pesticide. There are no other pets in the home. No further information expected. UPDATE 19 Nov 2019: The owner applied the 3rd dose of the product on 31 Oct. There is not change on the flea amount on her cats. No further medical information expected.
17-Oct-2019	UAE; 19US062727; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 3 lbs	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	15-Oct-2019*	17-Oct-2019	2 Day(s)	D-C	Suspected Adverse Event and Suspected Lack of Efficacy Claim: On 17 Oct 2019, the owner reported the following event for a 4 months old, 3 pound, intact feline (all other signalments unknown). 26 Sept 2019: The owner noted fleas. An unknown amount of FRONTLINE SPRAY (lot unknown, package unavailable) was applied over the pet. 15 Oct 2019*: The owner noticed more fleas. The owner poured an unknown amount of FRONTLINE SPRAY over the cat. 17 Oct 2019: The cat experienced lethargy, inability to walk, and jumpy nerves. The pet did not present to the clinic and no treatment was provided. There are 3 other cats in the home that received the product. One of those cats also experienced symptoms (see case 19US061993). No further medical information is expected.
22-Oct-2019	UAE; 19US062753; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 45 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Apr-2019*	23-Aug-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the pet owner reported the following event for a 14 years old, 45 pound, female canine of unknown signalment. Unknown: The pet has received FRONTLINE PLUS DOG for multiple years seasonally, April through November. Apr thorough Jul 2019: Owner applied monthly doses. 22 Aug 2019: The owner bought a 3 pack and applied FRONTLINE PLUS DOG 45-88 LBS(S61313AR), 1 vial topically between the shoulder blades seasonally. 24 Aug 2019*: Owner began seeing a moderate amount of fleas. 22 Sep 2019: The monthly dose was applied. 22 Oct 2019: The monthly dose was applied. Fleas have been seen continuously since 23 Aug 2019. The owner

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ED_005739D_00014391-00381

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											has not been noticing fleas off of the pet inside the home . The pet does have flea allergy dermatitis. The yard is fenced with grass. The pet has not presented to the veterinarian. The pet is mostly indoor. There a total of 1 canine in the household. No further medical information expected.
22-Oct-2019	UAE; 19US062762; WI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the owner reported the following event for a canine (all other signalments unknown). 1 Oct 2019: The first vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable) was applied for the first time between the shoulder blades, by the pet owner. 2 Oct 2019*: The dogs had small amount of fleas. The dog does not get bathed. The owner is not seeing any flea activity in the household. The dog likes to roll in the grass while on walks for bathroom breaks. It is unknown if fleas were seen before application. No further medical information is expected.
22-Oct-2019	UAE; 19US062768; CA; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 22.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Oct-2019	22-Oct-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the pet owner reported the following event for Desi, a 10 year old, 22.0 pound, neutered male Chihuahua mix. 5 Oct 2019: The pet owner applied 1 dose of FRONTLINE PLUS DOG 5-22 LBS (T60214AL), in one spot, between the shoulder blades, to the dog. 22 Oct 2019: The pet owner noticed approximately 20 live fleas on the dog and bathed the dog with a flea shampoo. She has not seen fleas since the bath. The dog frequents a dog park and a friend's yard that has 2 other dogs. There are no other pets in the home and no fleas have been seen in the home. The dog has received FRONTLINE PLUS DOG 5-22 LBS previously since 2017 with no issues. No further medical information expected.
22-Oct-2019	UAE; 19US062784; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	30-Sep-2019	22-Oct-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim and adverse event Claim : On 22 Oct 2019, the pet owner reported the following event for a male canine of unknown signalment. Unknown: The pet has received FRONTLINE PLUS DOG in the past with no adverse reactions. It is unknown at what interval it has been applied. 29 Sep 2019*: Owner noticed the pet itching, 1 live flea was seen. 30 Sep 2019: The owner applied FRONTLINE PLUS DOG (Lot unknown) (package unavailable) (product unsubstantiated), by an unknown method for the first time this year. 1 Oct 2019*: The itching seemed to resolve. 22 Oct 2019: Owner noticed the pet's itching increasing. No live fleas have been seen. It is unknown when the pet bathed and if it has any skin issues. The yard is fenced with grass. The pet has not presented to the veterinarian. The pet is indoor/outdoor. There a total of 1 canine in the household. No further medical information expected.
22-Oct-2019	UAE; 19US062799; MS; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	23-Sep-2019*	24-Sep-2019*	1 Day(s)	D-C	Suspected Lack of Efficacy Claim: On 22 October 2019, the following event was reported via email by a pet owner involving an unknown number of canines (signalment is unknown). 23 September 2019*: An application of FRONTLINE PLUS (unknown lot number and product unsubstantiated) was applied to unknown number of canines in the household. It was reported that

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ED_005739D_00014391-00382

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - **Weight:** Unknown				**used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					the owner has always used this product, but the frequency of use was not reported. 24 September 2019*: The reporter saw fleas on her pets. It is unknown if the pets had fleas prior to use. It is unknown if the animals go swimming or are bathed in a shampoo labeled for pets. It is unknown if the pets have any prior skin conditions and it us unknown how the product was applied. It was reported that the pet's skin is raw from irritation from the fleas. It is unknown if the pet owner is seeing fleas inside the home or if the pets are indoor or outdoor pets. No other details about this event are known, as there are no other details in the email. No other medical information is expected.
22-Oct-2019	UAE; 19US062812; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 10 - 12 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	04-Aug-2019	05-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the pet owner reported the following event for 3 felines of unknown signalment, ages 10-12 years old and weighing 10-12 pounds. History: The owner dealt with fleas about 5 years ago and FRONTLINE PLUS CATS got rid of the fleas right away. 4 Jun 2019: The owner applied FRONTLINE PLUS CAT (Lot unknown) (package unavailable), 1 vial per animal topically between the shoulder blades for the first time this seasonal. The pets are usually treated seasonally from June through November. 4 Aug 2019: The monthly dose is applied. 5 Aug 2019: The owner noticed a large amount of fleas on the pet. 4 Sep 2019: The monthly dose is applied. 4 Oct 2019: The monthly dose is applied. Fleas have been seen continuously since Aug 2019. The owner has not been noticing fleas off of the pets inside the home . The pets are not bathed and do not have any skin issues. The yard is fenced with grass. The pets have not presented to the veterinarian. The pets are indoor only. There a total of 3 felines in the household. No further medical information expected.
22-Oct-2019	UAE; 19US062816; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	Jun-2019*	22-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, a pet owner reported the following event for 2 felines of unknown signalment. Jun 2019*: The owner started FRONTLINE PLUS CATS (lot unknown, package unavailable) and applied 1 dose per cat on an unknown date. It is unknown if the cats had fleas prior to application. The owner applies monthly. Oct 2019: The cats still have fleas. All further details are unknown. No further medical information expected.
22-Oct-2019	UAE; 19US062866; AZ; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 40 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	03-Jul-2019*	25-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019 the owner reported the following event for a 40 pound* canine of unknown signalment. 3 Jul 2019*:The owner applied one vial of FRONTLINE PLUS DOG 23-44 LBS (P62208AL) topically between the shoulder blades for the first time. 3 Aug 2019*:The owner applied FRONTLINE PLUS to the pet. 25 Aug 2019*: Owner removed one live tick and one dead tick from the pet. The species of tick is unknown. 3 Sep 2019*: The owner applied FRONTLINE PLUS to the pet. The pet has access to a grass yard, it is unknown if wildlife is present. There are no other pets in the home. The pet is bathed on

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ED_005739D_00014391-00383

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					unknown dates with an unknown shampoo. The pet was in good health and has no history of reactions. No further medical information expected.
22-Oct-2019	UAE; 19US062869; NH; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.50 Year(s) **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Sep-2019	21-Oct-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the pet owner reported the following event for Mya, a 4.5 year old 15 pound female spayed Domestic Shorthair. 2018*: The pet began receiving FRONTLINE PLUS CAT (Lot unknown)(package unavailable), applied 1 vial topically between the shoulder blades seasonally April through November . 17 Sep 2019: The pet received her monthly dose, FRONTLINE PLUS CAT(S41307AW) 14 Oct 2019: Owner removed 2 attached engorged ticks. It is unknown if they were alive and what species it was. 16 Oct 2019: The monthly dose was applied. 21 Oct 2019: The owner found 3 attached, engorged ticks. The ticks' species are unknown. The environment is wooded. No further medical information expected.
22-Oct-2019	UAE; 19US062879; NH; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	20-Oct-2019	21-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the pet owner reported the following event for a male Australian Shepard of unknown signalment. Apr 2019*: The pet began receiving FRONTLINE PLUS (Lot unknown)(package unavailable)(product unsubstantiated), applied 1 vial topically between the shoulder blades for the first time this season. 20 Oct 2019*: The monthly dose was applied a few days late. 21 Oct 2019: The owner found an attached, engorged tick. The environment is wooded. The tick species in unknown. It is unknown if the tick is alive or dead. No further medical information expected.
23-Oct-2019	UAE; 19US062897; IN; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jun-2019	02-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for a 10 year old*, 10 pound*, female feline of unknown breed and reproduction status. 2014*: The pet began receiving FRONTLINE PLUS CAT (Lot unknown) (package unavailable) 1 vial topically between the shoulder blades monthly. 1 Jun 2019: The owner bought an 8 pack of FRONTLINE PLUS CAT (Lot unknown) (package unavailable) from Costco. The monthly dose was applied. 2 Jun 2019*: Owner began seeing fleas. 1 Jul 2019: The monthly dose was applied. 1 Aug 2019: The monthly dose was applied. 1 Sep 2019: The monthly dose was applied. 1 Oct 2019: The owner bought an 6 pack of FRONTLINE PLUS CAT (Lot unknown) (package unavailable) from Chewy. The monthly dose was applied. Oct 2019*: The pet was bathed with cat shampoo. Fleas have been seen continuously since Jun 2019. The owner has not been noticing fleas off of the pet inside the home . It is unknown if the pet has any skin issues. The pet is indoor/outdoor and has access to a golf course with a lot of wildlife. The pet has not presented to the veterinarian. There a total of 1 feline in the household. No further medical information expected.

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ED_005739D_00014391-00384

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
23-Oct-2019	UAE; 19US062899; NC; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** - **Age:** 6.00 Month(s) **Weight:** 7 lbs	6	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** EPRINOMECTIN 0.4% / PRAZIQUANTEL 8.3% SOLUTION; **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Aug-2019*	23-Oct-2019*	7 Week(s) 3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the office manager reported the following event for Smokey, a 6 month old (born 15 Apr 2019), 7 pound, intact male, domestic shorthair crossbreed feline. 1 Aug 2019: Tapeworms were observed in the cat's stool by the clinic. The cat was treated with CENTRAGARD 5.6 -16.5 LBS (CUS001DAA, Jan 2020) topically, between the shoulder blades, by the veterinarian. 9 Sep 2019: Tapeworms were observed in the cat's stool by the clinic again. Another dose of CENTRAGARD was applied. The owner is still seeing tapeworms in the stool, but it has not yet been verified by the clinic. The owner also said they have been applying FRONTLINE PLUS CATS (lot unknown, package unavailable) but all information about the product and applications is unknown as the owner is not getting the product from the clinic. No fleas have been seen on the cat. The owner has 5 other cats that also received the products and are not having any problems. The cats are strictly indoor. No further medical information expected. UPDATE 30 Oct 2019: per the records received, the cat received the second dose of CENTRAGARD on 11 Sep 2019, not 9 Sep 2019 as previously reported. No further medical information expected.
23-Oct-2019	UAE; 19US062901; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** - **Age:** 8.00 Month(s) **Weight:** 7 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	02-Oct-2019	1 Day(s)	D-C	Suspected Adverse Event: On 23 Oct 2019, the pet owner reported the following event for Shrimp, 7 pounds*, 8 month, intact male, Domestic Shorthair. 01 Oct 2019: The pet owner applied the contents of 1 vial FRONTLINE PLUS CATS (S41404AW) to the skin between the shoulder blades for the first time. 02 Oct 2019: The pet excessively scratched at the application site to cause fur loss, irritation, and scabbing. The owner applied antibacterial cream to it daily. 06 Oct 2019*: The owner's clinic suggested to wipe the product off with a warm rag. 23 Oct 2019: The issue has not fully resolved, but itchiness has decreased. No further medical information expected.
23-Oct-2019	UAE; 19US062903; NY; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 25 - 40 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Aug-2019*	08-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for Maggie, a 7 year old, 25 pound, female canine of unknown breed and Dozer, a 2 year old, 40 pound canine of unknown breed. History: The pets have received FRONTLINE PLUS DOG seasonally Apr through Nov for multiple years. 7 Apr 2019*: The owner applied FRONTLINE PLUS (Lot unknown) (package unavailable) 1 vial per animal topically between the shoulder blades for the first time this season. 7 Aug 2019*: The monthly dose was applied, FRONTLINE PLUS (S61727AL) 8 Aug 2019*: The owner noticed a moderate amount of fleas on the pets. Aug 2019: The owner gave the pets baths in Dawn every other week throughout the month. 7 Sep 2019: The monthly dose was applied. 7 Oct 2019: The monthly dose was applied. Fleas have been seen continuously since Aug 2019. The owner has been noticing fleas off of the pet inside the home. The pets were not bathed in Sep or Oct. The pets have dry skin currently.

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											The yard is fenced with grass. The pets have not presented to the veterinarian. The pets are indoor/outdoor. There a total of 2 canines in the household. No further medical information expected.
23-Oct-2019	UAE; 19US062904; OH; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 7 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Aug-2019	11-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the owner reported the following event for a 7 pounds, Chihuahua (all other signalments unknown). Aug 2019: The dog started on FRONTLINE PLUS on a monthly basis. 10 Oct 2019: The most recent vial of FRONTLINE PLUS DOG 5-22 LBS (R62514BL) was applied between the shoulder blades, by the pet owner. 11 Oct 2019: The dog had moderate amount of fleas for the first time. The dog does not get bathed. The owner is not seeing any flea activity in the household. The owner washed the dog bedding and vacuumed the home. The dog has access to an unknown area for bathroom breaks. There is 1 other dog in the household using FRONTLINE PLUS as well with case 19US063971. No further medical information is expected.
23-Oct-2019	UAE; 19US062906; MA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 12 lbs	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	23-Oct-2019	23-Oct-2019	0 Day(s)	D-B	Suspected Adverse Event: On 23 Oct 2019, the technician reported the following event for Bela, an 11 year old (14 Aug 2008), 12 pound, neutered male Domestic Shorthair. 23 Oct 2019: The cat received FRONTLINE SPRAY (lot and expiration unknown, package unavailable). It is unknown how many sprays were applied. Within 10-15 minutes, the cat began hiding around the house and began experiencing vocalizing loudly, hypersalivating, urinated and defecated on himself, and labored breathing. The cat presented to the veterinary clinic. The cat presented with pale mucous membranes and a low temperature of 99.4°F. Radiographs were performed, revealing a possible abdominal mass. The radiographs were submitted to a radiologist for evaluation, results unknown. Bloodwork was performed, results unknown. Treatment was started with IV fluids. It is unknown if further treatment has been provided. The cat is currently under treatment at the hospital. It is unknown if the cat previously received the product. The veterinarian has a low suspicion that the product caused the reaction. No further medical information expected.
23-Oct-2019	UAE; 19US062937; VA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	5	5	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-May-2019*	01-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for 5 cats of unknown signalment. 1 May 2019*: The cats began receiving FRONTLINE PLUS CATS (S41003AW) monthly. The product was applied directly on the skin between the shoulder blades. Fleas were seen prior to product application. 21 Oct 2019: The most recent date of application. 23 Oct 2019: The owner is still noticing an unknown amount of fleas. Three of the cats do go outside on occasion, two of the cats are indoor only. The pet owner is seeing indoor flea activity in the home. No treatments have been provided at home. The cats' current conditions are ongoing. These are the only pets in the household. No further medical information expected.
23-Oct-2019	UAE; 19US062947;	**Species:** Canine **Breed:** Schnauzer	1	1	0	**Product used:** FIPRONIL	01-Jul-2019*	15-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019 a pet owner called to report the following information in Murphy Lee, a 10 year

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ED_005739D_00014391-00386

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	OH; U.S.A	**Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 31 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					old (31 May 2009), 31 pound*, neutered male, Schnauzer breed canine. 1 Jun 2009*: The dog began receiving one dose of FRONTLINE PLUS DOG 23-44LBS (Lot and expiration date unknown, package unavailable) in between the shoulder blades monthly, year round with the most recent application on 1 Jul 2019*. 15 Jul 2019*: The pet owner discovered the dog had fleas. 12 Oct 2019*: The pet owner continued to see fleas, they have never stopped since 15 Jul 2019*. The pet owner bathed the dog in Dawn dish soap. 23 Oct 2019: The pet owner continues to see fleas, they have not stopped. The dog has access to a back yard where feral cats visit. There are no other animals in the home. No further medical information expected.
23-Oct-2019	UAE; 19US062951; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 40 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	21-Oct-2019	23-Oct-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for a 1 year old, 40 pound male canine of unknown breed. 21 Oct 2019: The pet began receiving FRONTLINE PLUS 45-88 LBS (Lot unknown)(package unavailable), applied 1 vial topically between the shoulder blades for the first time. 23 Oct 2019: The owner found an attached tick. The environment is unknown. It is unknown if the tick was alive or dead. The tick species in unknown. No further medical information expected. UPDATE 23 Oct 2019: Per owner, the dog has access to a heavily wooded area. The dog had deer ticks attached and walking throught the fur. No further medical information expected. UPDATE 2 DEC 2019: corrected VeDDRA code to LOE.
23-Oct-2019	UAE; 19US062961; MN; U.S.A	**Species:** Feline **Breed:** Feline various breeds **Sex:** X **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 7 - 11 lbs	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Sep-2019*	03-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim and Adverse Event: On 23 Oct 2019, the pet owner reported the following event for Fluffy, a spayed female, 11 pound, 10 year old, Maine Coon. Mr. Black, a neutered male, 8 pound, 3 year old, Domestic Shorthair. Mr. Friendly, a neutered male, 7 pound, 3 year old, Domestic Shorthair. Malooga, a spayed female, 10 pound, 7 year old, Domestic Shorthair. 1 Sep 2019*: Ticks were noticed prior. 2 Sep 2019*: The patient got their monthly dose of FRONTLINE PLUS CATS LBS(S41305). The cats have gotten it monthly for their whole lives, exact dates are unknown. The owner purchased a 3 pack this past purchase. It was applied between the shoulder blades. 3 Sep 2019*: The owner noticed ticks occasionally on the animals. The pets do go outside. The ticks are removed if possible. The ticks are alive, the ticks have not been identified. The pet is showing some skin issues, no redness or sores but the cats seem to be irritated by FRONTLINE just being on their being on their skin each time it is applied. No ticks in the home, but she did have one tick her. The patient's current condition is ongoing. There is a total of 4 felines in the household. No further medical information expected.
23-Oct-2019	UAE; 19US062963; WV; U.S.A	**Species:** Canine **Breed:** Canine (unknown)	2	2	0	**Product used:** FIPRONIL 10%/S	01-Jul-2019*	12-Jul-2019*	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner mailed in and reported the following for two dogs of unknown signalment.

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		Sex: U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					1 Jul 2019*: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (unsubstantiated) (lot unknown, package unavailable). An unknown volume per animal via an unknown route at an unknown location. 12 Jul 2019*: Pet owner seeing an unknown amount of fleas on the dogs. It is unknown if they presented to a veterinary clinic. It is unknown if any treatments have been administered. Their current condition is unknown. It is unknown what environment the canines frequent. It is unknown if the owner bathes the canines. It is unknown if there are any other pets in the household. It is unknown if the dogs received FRONTLINE PLUS previously. This is the extent of information known as caller refused to report. No further medical information expected.
23-Oct-2019	UAE; 19US062985; GA; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 85 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Sep-2019	15-Sep-2019*	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for Dixie, a 6 year old, 85 pound, neutered male, Golden Retriever. 1 Aug 2018*: The dog began receiving FRONTLINE PLUS DOG 45-88 LBS (S60719AX) monthly. The product was applied directly on the skin between the shoulder blades. 5 Sep 2019: The most recent date of application. 15 Sep 2019*: The owner is noticing a large amount of fleas. The dog has also been scratching. The dog has access to an outside area, with trees and brush on the property. The pet owner has not seeing any indoor flea activity. 20 Sep 2019*: The dog presented to the veterinary clinic. No diagnostics have been performed. Treatments have been initiated with an unknown oral antibiotic. The dog's current condition is ongoing. There are three cats also in the household, who are on a non-company flea product, with no fleas noted. No further medical information expected.
23-Oct-2019	UAE; 19US062999; NC; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Mixed **Age:** 16.00 Week(s) **Weight:** 12 - 14 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Sep-2019	Oct-2019*	5 Week(s) 5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for Chase, a 16 week old, 14 pound, female intacted, German Shepard and Miley a 6.5 year old, 12 pound, female spayed Miniature Pinscher. 21 Sep 2019: The owner bought a 6 pack and applied FRONTLINE PLUS 5-22 LBS (T60214AL), 1 vial per animal topically between the shoulder blades for the first time. No live fleas were seen at this time. Oct 2019*: The owner noticed a small amount of flea dirt on Chase. Chase has presented to the veterinarian due to increase in scratching. The veterinarian started him on an unknown oral flea and tick medication. 21 Oct 2019: Owner saw a live flea on Miley and she has flea bites. The owner has not seen continuously. The owner has been noticing fleas off of the pet inside the home. The pets are not bathed and do not have any skin issues. The yard is fenced with grass. The pets are indoor/outdoor. There a total of 2 canines in the household. No further medical information expected.
23-Oct-2019	UAE; 19US063000; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** X	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON	02-May-2019*	23-Oct-2019*	3 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019 a pet owner called to report the following event in 2 cats, one spayed female, and one neutered male, each 12 years old, and 10 pounds*. 15 Apr 2019*: The pet owner discovered her two cats had fleas. 2 May 2019*: The pet owner started to apply FRONTLINE PLUS

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ED_005739D_00014391-00388

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Neutered **Age:** 12.00 Year(s) **Weight:** 10 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					(G41602BW) to the cats in unknown locations for the first time this year monthly with the most recent application on 2 Oct 2019*. 23 Oct 2019: The pet owner has not stopped seeing fleas since she applied the FRONTLINE PLUS on 2 May 2019*. The cats are indoor only. There are no other animals in the home. The pet owner refused additional information. No further medical information expected.
23-Oct-2019	UAE; 19US063020; NY; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jun-2019*	26-Jun-2019	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for a male feline. All other signalment is unknown. Unknown Date: The pet owner applied an unknown amount of FRONTLINE PLUS CATS(S41004AW), to an unknown location on the cat. 26 Jun 2019: The pet owner saw live, attached ticks on the cat. 8 Jul 2019, 17 Jul 2019 and 30 Jul 2019: The pet owner continued to see ticks on the cat. The pet owner has used FRONTLINE PLUS CATS previously on unknown dates with no issues. All other details are unknown. No further medical information expected.
23-Oct-2019	UAE; 19US063026; NY; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 19 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Sep-2015*	01-Oct-2019*	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for Max, a 14 year old, 19 pound, male neutered Domestic Shorthair. History: The pet began receiving FRONTLINE PLUS CAT (Lot unknown) (package unavailable) monthly year round for many years with no fleas seen. 16 Sep 2019: The owner bought a 6 pack and applied FRONTLINE PLUS CAT (S40210CW), 1 vial topically between the shoulder blades monthly. 1 Oct 2019*: The owner noticed the pet scratching more than normal. The pet presented to the veterinarian who saw a small amount of fleas on the pet. The veterinarian applied a dose of Revolution. 23 Oct 2019: The owner is no longer seeing fleas The owner has not been noticing fleas off of the pet inside the home. The pet is not bathed and does have skin issues due to compulsive over-grooming. There is a total of 2 felines in the household. The pets are indoor/outdoor. The other pet is treated with FRONTLINE PLUS CAT and no fleas are being seen on this pet. No further medical information expected.
23-Oct-2019	UAE; 19US063028; CA; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jul-2019*	15-Jul-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for 2 dogs of various breeds, 12 to 14 years, all other signalments unknown. 01 Jul 2019*: The owner applied FRONTLINE PLUS DOG 5-22 LBS (product unsubstantiated) (lot unknown/ package unavailable) to an unknown location in an unknown manner unknown if this is the first time. 15 Jul 2019*: The owner noticed an unknown quantity of live fleas on the dogs. 23 Oct 2019: The owner reports continuing to see an unknown quantity of live fleas on the dogs. There are also 2 cats in the home on FRONTLINE PLUS unknown if live fleas are seen. The pets are outdoor for short periods of time. The owner is treating the dogs with an unknown hot spot

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* indicates Approximate date or weight.

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ED_005739D_00014391-00389

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											relief, calming spray, and flea spray. The owner has had the yard treated with an unknown spray. No further medical information expected.
23-Oct-2019	UAE; 19US063041; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	23-Oct-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, a pet owner reported the following event for a canine of unknown signalment. Jun 2019*: The owner applied FRONTLINE PLUS DOG (product unsubstantiated)(lot unknown, package unavailable) it is unknown if fleas were present. The owner applies monthly. 23 Oct 2019: The owner saw a few live fleas. All other details are unknown. NO further medical information expected.
23-Oct-2019	UAE; 19US063047; IA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	04-Oct-2019	05-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the owner reported the following event for 2 canines (all other signalments unknown). Apr 2019: The canines started on the FRONTLINE PLUS on a monthly basis. 4 Oct 2019: The most recent vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, reporter not queried) was applied between the shoulder blades, by the pet owner. 5 Oct 2019*: The dogs had fleas. The dogs do not get bathed. The owner is not noticing any flea activity in the household. The dogs go on walks for bathroom breaks. No further medical information is expected.
23-Oct-2019	UAE; 19US063060; MN; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 12 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	10-May-2019*	23-Oct-2019	5 Month(s) 2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for an unknown amount of dogs of unknown signalment. 10 May 2019*: The owner applied FRONTLINE PLUS DOG 5-22 LBS (S62502AW) in an unknown manner to an unknown location. 23 Oct 2019: The owner reports seeing an unknown quantity of an unknown species of live ticks on the pet. Dates and other details are unknown as the owner provided very limited details in a hand written note. No further medical information expected. UPDATE 2 Jan 2020: Per the pet owner May 2019*: The owner noticed an unknown amount of ticks on the pet. 10 May 2019* through 10 Jul 2019*: The owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS to the pet. The owner continued to notice live and dead unknown species of ticks on the pets nose and neck area. The pets signalment is a 3 year old*, 12 pound*, neutered male, Maltese. The pet has access to a large wooded peice of property, where urban wildlife is present. It is unknown if the pet is bathed. The condition of the pet is unknown. No further medical information is expected.
23-Oct-2019	UAE; 19US063064; IL; U.S.A	**Species:** Feline **Breed:** Feline (unknown)	1	1	0	**Product used:** FIPRONIL SPRAY	01-Oct-2019*	23-Oct-2019*	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for LT, a female feline, of further unknown signalment.

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ED_005739D_00014391-00390

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					Unknown Date: The pet owner noticed fleas on the cat. The pet owner applied FRONTLINE SPRAY (lot unknown, Reporter not queried), to the cat. It is unknown how the FRONTLINE SPRAY was applied. The pet owner continues to see fleas. It is unknown how many fleas he sees. The pet owner has used FRONTLINE SPRAY and FRONTLINE PLUS CATS previously with reported issues (See Case 19US059224). There are 2 other cases of FRONTLINE SPRAY (See Cases 19US063069 and 19US093084). It is unknown how many cats are in the home. No further information expected. UPDATE 23 Oct 2019: Per owner call, owner stated he had 6 cats in total in the household. No further information is expected.
23-Oct-2019	UAE; 19US063068; TN; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Month(s) **Weight:** 2 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-May-2019*	01-Jun-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for a 3 month old*, 2 pound*, female spayed feline of unknown breed. May 2019*: The owner adopted the pet and noticed a small amount of fleas on the pet. The owner bought a 3 pack and applied FRONTLINE PLUS CAT (Lot unknown) (package unavailable) by an unknown method monthy. Jun and Jul 2019: The monthly doses were applied. Fleas have been seen continuously since May 2019. The owner has been noticing fleas off of the pet inside the home . It is unknown if the pet is bathed and unknown if she has any skin issues. The pet has not presented to the veterinarian. The pet is indoor only. There a total of 1 feline in the household. No further medical information expected.
23-Oct-2019	UAE; 19US063069; IL; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for Cody, a feline. All other signalment is unknown. Unknown Date: The pet owner noticed the cat had fleas and was scratching his ear. The pet owner applied an unknown amount of FRONTLINE SPRAY (lot unknown, Reporter not queried), to the cat. It is unknown how the FRONTLINE SPRAY was applied. Unknown Date: The pet owner still notices fleas and the cat has continued to scratch his ear which has caused a hematoma. It is unknown how many fleas he sees. The pet owner has used FRONTLINE SPRAY and FRONTLINE PLUS CATS previously with reported issues (See Case 19US059224). There are 2 other cases with FRONTLINE SPRAY (See Cases 19US063064 and 19US063084). It is unknown how many cats are in the home. No further information expected. UPDATE 23 Oct 2019: Per owner call, owner stated he had 6 cats in total in the household. No further medical information is expected. UPDATE 11 NOV 2019: Upon internal revuew corrected patient count numbers to 1.
23-Oct-2019	UAE; 19US063074; CA; U.S.A	**Species:** Canine **Breed:** Akita **Sex:** U **Sex qualifier:** - **Age:** 5.00 Month(s) **Weight:** 70 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	16-Oct-2019*	22-Oct-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for a 5 month, 70 pound, Akita, with remaining signalment unknown. 1 Jul 2019*: The dog began receiving FRONTLINE PLUS DOG 45-88 LBS (S62503AX) monthly. The product was applied directly on the skin between the shoulder blades. 16 Oct 2019*: The most recent date of application. 22 Oct 2019*: The owner noticed fleas. The dog has access to a large open property, with trees and brush on the property. The pet owner reports the dog spends time in a barn, with lots of wildlife

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ED_005739D_00014391-00391

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					passing through the property. The dog presented to the veterinary clinic. No diagnostics have been performed. Treatments have been initiated with a medicated shampoo, an unknown injection, an unknown oral medication, and NEXGARD. The dog's current condition is ongoing. There are three other dogs in the household, all are treated with FRONTLINE PLUS, one other dog has a report of fleas (See case 19US063100). No further medical information expected.
23-Oct-2019	UAE; 19US063080; CT; U.S.A	**Species:** Canine **Breed:** Poodle (Standard) **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 40 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Oct-2019	21-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for Charlie, a 6 year old, 40 pound, male neutered Poodle. 2015*: The pet began receiving FRONTLINE PLUS DOG 23-44 LBS (Lot unknown) (package unavailable), 1 vial topically between the shoulder blades monthly. 20 Oct 2018: The monthly dose was applied, FRONTLINE PLUS DOG 23-44 LBS (S60801AL). 21 Oct 2019: The owner noticed 1 flea on the pet. The owner has not seen any more fleas. The owner has not been noticing fleas off of the pet inside the home. The pet is bathed every 8 weeks with dog shampoo and does not have any skin issues. The yard is grassy with wildlife present. The pet has not presented to the veterinarian. The pet is indoor/outdoor. There a total of 1 canine in the household. No further medical information expected.
23-Oct-2019	UAE; 19US063084; IL; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	02-Oct-2019*	1 Day(s)	D-C	Suspected Adverse Event: On 23 Oct 2019, the pet owner reported the following event for Fancy, a feline. All other signalment is unknown. Unknown Date: The pet owner applied an unknown amount of FRONTLINE SPRAY (lot unknown, Reporter not queried), to the cat. It is unknown how the FRONTLINE SPRAY was applied. Unknown Date: The pet owner noticed the cat was off balance, having issues with jumping and muscle control. It is unknown if the cat presented to a veterinary clinic or if the cat was treated. It is unknown if the cat is recovered. Specific details are not known. The pet owner has used FRONTLINE SPRAY and FRONTLINE PLUS CATS previously with a reported adverse reaction (See Case 19US059224). There are 2 other lack of efficacy cases with FRONTLINE SPRAY (See Cases 19US063064 and 19US063069). It is unknown how many cats are in the home. No further medical information expected.
23-Oct-2019	UAE; 19US063093; -; U.S.A	**Species:** Canine **Breed:** Poodle (Toy) **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 7.7 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019*	02-Oct-2019*	1 Day(s)	D-B	Suspected Adverse Event: On 23 Oct 2019, the veterinary student reported the following event for Avi, a 11 year old, 7.7 pound, neutered male Poodle (Toy) mix. *Unknown date: One vial of FRONTLINE (product unsubstantiated, lot unknown, packaging unavailable) was given topically. *Unknown date: The dog developed seizure like activity and recovered without vet assistance. No further information available.

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ED_005739D_00014391-00392

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
23-Oct-2019	UAE; 19US063098; -; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 84 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for an 84 pound, German Shepherd of further unknown signalment. Unknown date: The patient got their dose of FRONTLINE PLUS DOG 45-88 LBS(lot unknown, reporter refused). It is unknown how long the dog was on FRONTLINE, or if fleas were seen before this last dose. It is unknown how it was applied. Unknown Date: The owner noticed fleas on the animal. It is unknown if the pet goes outside or how often. It is unknown if the dog is having any skin issues. It is unknown if the animal gets bathed. It is also unknown if any fleas have been seen in the home or on the owner. The patient's current condition is ongoing. The Total number of animals in the house is unknown. The owner was primarily calling to ask if she should give another dose and if she could combine the use of FRONTLINE with a flea and tick collar going forward. No further medical information expected.
23-Oct-2019	UAE; 19US063100; CA; U.S.A	**Species:** Canine **Breed:** Akita **Sex:** U **Sex qualifier:** Unknown **Age:** 5.00 Month(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Oct-2019*	22-Oct-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for a 5 month, Akita, with remaining signalment unknown. 1 Jul 2019*: The dog began receiving FRONTLINE PLUS DOG 45-88 LBS (S62503AX) monthly. The product was applied directly on the skin between the shoulder blades. 16 Oct 2019*: The most recent date of application. 22 Oct 2019*: The owner noticed fleas. The dog has access to a large open property, with trees and brush on the property. The pet owner reports the dog spends time in a barn, with lots of wildlife passing through the property. No treatments have been provided at home. The dog's current condition is ongoing. There are three other dogs in the household, all are treated with FRONTLINE PLUS, one other dog has a report of fleas (See case 19US063074). No further medical information expected.
23-Oct-2019	UAE; 19US063109; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for an canine of unknown signalment. Unknown date: The patient got their dose of FRONTLINE PLUS DOG (lot unknown, reporter refused). It is unknown how long the dog was on FRONTLINE, or if fleas were seen before this last dose. It is unknown how it was applied. Unknown Date: The owner noticed fleas on the animal. It is unknown if the pet goes outside or how often. It is unknown if the dog is having any skin issues. It is unknown if the animal gets bathed. It is also unknown if any fleas have been seen in the home or on the owner. The patient's current condition is ongoing. The Total number of animals in the house is unknown. Owner primarily calling to ask if NEXGARD she got to use in place of the FROTNLINE is still good. Dog has not had NEXGARD yet. No further medical information expected.
23-Oct-2019	UAE; 19US063114; OR; U.S.A	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** M **Sex qualifier:** - **Age:** - **Weight:** 18.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	25-Sep-2019	16-Oct-2019*	3 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following issue with Checker, an 18.0 pound, intact male Jack Russell Terrier. Unknown Date: The pet owner noticed the dog was itching and saw fleas on the dog. 25 Sep 2019: The pet owner applied 1 dose of FRONTLINE PLUS DOG 5-22 LBS (S61912AL), to an unknown location on the dog. 16 Oct 2019*: The pet owner noticed 4 to 5 live fleas on the dog.

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ED_005739D_00014391-00393

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous **Was the product used ok?:** Unknown to Company					The dog goes for walks and the pet owner noted that there are other dogs along the route. The dog has previously been treated with FRONTLINE PLUS, with no issues. There are no other pets in the home. This is the extent of information. No further information expected.
23-Oct-2019	UAE; 19US063125; VA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	20-Oct-2019	23-Oct-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, an owner reported the following event in 4 cats of unknown further signalment. 20 Oct 2019: The owner administered one FRONTLINE PLUS CATS (S41305AW) topically, to each cat, at the base of the skull as part of a year round, monthly preventative. No fleas were seen at the time of application. 23 Oct 2019: The cats are scratching and biting, the owner believes to be due to fleas. The cats all have flea dirt on them but no visible fleas. The owner is finding red blood specks from flea dirt in her bed. The cats are indoor-outdoor in an unknown environment. There are no other animals in the home. The status of the cats is unknown. No further medical information expected.
14-Oct-2019	UAE; 19US063126; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 19.00 Year(s) **Weight:** 10.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	06-Sep-2019	14-Sep-2019*	N/A	D-D	Suspected Adverse Event: On 14 Oct 2019, the pet owner reported the following event for a 19 year old, 10.0 pound, feline. All other signalment is unknown. 6 Sep 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S41004AW), in an unknown location, to the cat. Fleas were not seen prior to product application. 14 Sep 2019*: The pet owner noticed fleas on the cat. 6 Oct 2019: The pet owner bathed the cat with an unknown pet shampoo and the most recent dose of FRONTLINE PLUS CATS was applied. The pet owner is currently seeing approximately 5 fleas on the cat. The cat does not go outside. There is a dog in the home that receives FRONTLINE PLUS DOG 5-22 LBS and is experiencing issues with fleas (See Case 19US061079). The pet owner occasionally sees fleas in the home. The cat has received FRONTLINE PLUS CATS previously since Apr 2019, on unknown dates. The cat has missed a dose in either Jul or Aug. No further medical information expected.
23-Oct-2019	UAE; 19US063128; -; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 82 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	30-Sep-2019*	21-Oct-2019	3 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, animal owner reported the following event for Madison, a 9 year old, 82 pound, spayed female,German Shepherd dog. *2011: Started monthly FRONTLINE PLUS DOG 89-132 LBS (Lot unknown/ package unavailable) topically between the shoulder blades. *May 2019: A dose was applied. *June 2019: The dog started exhibiting swollen ankles and limping. These symptoms were on and off for several months. *30 Sep 2019: A dose was applied. 21 Oct 2019: the dog presented for swollening ankles and limping. The dog tested positive for lyme disease on an unknown test. The pet owner noted never seeing ticks on the dog. Treatments and diagnostics are unknown. All additional information was unknown. No further information expected at this time.
23-Oct-2019	UAE;	**Species:** Canine	2	2	0	**Product used:**	17-Oct-2019	23-Oct-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner

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ED_005739D_00014391-00394

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19US063130; CA; U.S.A	**Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown flea/tick shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					reported the following event for 2 canines of unknown signalment. 16 Oct 2019: The pets received a flea and tick bath at the groomers after seeing an unknown quantity of an unknown species of tick after boarding on a farm. 17 Oct 2019: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 45-88 LBS (R62001AR) to the skin between the shoulder blades for the first time. 19 Oct 2019: The owner noticed several dead tick fall off the pets. 20 Oct 2019*: The dogs tested negative on an unknown test for tick borne diseases at the veterinary clinic. 23 Oct 2019: The owner reports continuing to see 1 to 2 live attached ticks on one of the dogs which the owner removes. There are no other pets in the home. The owner is seeing live ticks in the home. The dogs do go on walks in the neighborhood. No further medical information expected.
23-Oct-2019	UAE; 19US063134; MO; U.S.A	**Species:** Canine **Breed:** Spaniel (King Charles) **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 30.0 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Adams flea spray; Unknown shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	27-Aug-2019	28-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 24 Oct 2019, the pet owner reported the following event for Bolt, a 3 year old, 30.0 pound*, male King Charles Spaniel. Aug 2019*: The pet owner took the dog camping. After returning home, the pet owner noticed fleas on the dog, but none in the home. The pet owner bathed the dog in a pet approved shampoo and sprayed the house and the dog's bedding with Adams flea spray. 27 Aug 2019: The pet owner applied 1 dose of FRONTLINE PLUS DOG 23-44 LBS (lot unknown, Reporter not queried), in one spot, between the shoulder blades on the dog, for the first time. Unknown Date: The dog began to scratch. 20 Sep 2019: The most recent dose was applied and the dog began to scratch more. 21 Sep 2019*: The pet owner still saw fleas and sprayed the dog with Adams flea spray and gave the dog a bath with an unknown shampoo. The pet owner is currently still seeing fleas. The dog has access to a backyard in the country, where groundhogs are kept and deer frequent the area. There are no other pets inside the home. No further medical information expected.
24-Oct-2019	UAE; 19US063145; NH; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 13 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	18-Oct-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the owner reported the following event for a 13 pounds, male, Domestic Shorthair (all other signalments unknown). 1 May 2019: The cat started on the FRONTLINE PLUS on a monthly basis. 1 Oct 2019: The most recent vial of FRONTLINE PLUS CATS (S41003AW) was applied between the shoulder blades, by the pet owner. 18 Oct 2019: The cat had ticks. The owner stated that the ticks were engorged upon removal but not sure if alive. The type of tick is unknown. The cat does not get bathed. The owner is not noticing any ticks in the household. The cat is an indoor/outdoor cat. No further medical information is expected.
24-Oct-2019	UAE; 19US063155; OH; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products**	05-Oct-2019	05-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 24 Oct 2019, the pet owner reported the following event for a 1 year old*, 8.0 pound*, spayed female feline. All other signalment is unknown. 5 Oct 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S41004AW), in one spot, between the shoulder blades, to the cat. An unknown amount of time later, the same date, the cat

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ED_005739D_00014391-00395

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 1.00 Year(s) **Weight:** 8.0 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					began foaming at the mouth. The cat has previously received FRONTLINE PLUS CATS monthly, year round, with no issues since 2018. The pet owner is not sure if the cat may have gotten into toothpaste, because she could smell toothpaste on the cat. The cat is in good health and is recovered. No further medical information expected.
24-Oct-2019	UAE; 19US063193; PA; U.S.A	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	13-Oct-2019	20-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, an owner reported the following event in Lily, a 9 year old, 10 pound, spayed, female, miniature Poodle canine. 13 Oct 2019: The owner administered one FRONTLINE PLUS DOGS 5-22 LBS (S61006AL) topically in-between the shoulders as part of a monthly, seasonal preventative. No fleas or ticks were seen at the time of application. 20 Oct 2019: The dog has had 1-4 ticks crawling on the dog and chair she sits on, daily. They are alive but not attached to the dog. The dog is indoor-outdoor in an unknown environment. There are no other animals in the home. The status of the dog is unknown. No further medical information available.
24-Oct-2019	UAE; 19US063205; TX; U.S.A	**Species:** Canine **Breed:** Schnauzer **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 19 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	20-Oct-2019	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the pet owner reported the following event for Wilson, a 8 year old, 19 pound*, neutered male, Terrier and Schnauzer Mix. 1 Oct 2016*: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (T60214AL) monthly year round. The product was applied directly on the skin between the shoulder blades. 1 Oct 2019: The most recent date of application. 20 Oct 2019: The owner noticed three alive ticks on the dog. The dog has access to a fenced in yard and open area, with trees and brush on the property. No treatments have been provided at home. The dog's current condition is ongoing. There are no other pets in the household. No further medical information expected.
24-Oct-2019	UAE; 19US063219; NH; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Capstar; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Jul-2019	24-Oct-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the pet owner reported the following event for 4 cats with unknown signalment. 20 Jul 2019: The cats began receiving FRONTLINE PLUS CATS (lot unknown, package unavailable) monthly. The product was applied directly on the skin between the shoulder blades. 24 Jul 2019*: The pet owner reports seeing an unknown amount of fleas. The cats presented to the veterinary clinic. Treatments were initiated with Capstar. 20 Aug 2019*: The pet owner applied the product. 20 Sep 2019: The most recent date of application. 24 Oct 2019: The owner is still noticing an unknown amount of fleas. The cats do have access to an open area outside, with trees and brush on the property. The cats' current conditions are ongoing. There is a dog in the household, who is on FRONTLINE PLUS, with a report of fleas (see Case 19US063233). No further medical information expected.
24-Oct-2019	UAE; 19US063226; TN; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	10-Sep-2019	11-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the pet owner reported the following event for Brinkley, a 7 year old, 10 pound, female spayed Shih Tzu . Unknown: The pet has received FRONTLINE PLUS DOG 5-22 LBS(Lot unknown) (package unavailable), 1 vial topically between

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ED_005739D_00014391-00396

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 7.00 Year(s) **Weight:** 10 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					the shoulder blades monthly. 10 Sep 2019: The monthly dose was applied. 11 Sep 2019: The owner noticed a few fleas on a chair that the pet lays on. 10 Oct 2019: The owner applied the monthly dose. 24 Oct 2019: The pet was taken to the groomer and they removed about 15 fleas. Fleas have not been seen continuously during this time. The pet is bathed regularly with dog shampoo and does not have any skin issues. The yard is fenced with grass. The pet has not presented to the veterinarian. The pet is indoor/outdoor. There a total of 1 canine in the household. No further medical information expected.
24-Oct-2019	UAE; 19US063233; NH; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	20-Oct-2019	24-Oct-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the pet owner reported the following event for a canine with unknown signalment. 20 Oct 2019: The dog received FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable). The product was applied directly on the skin between the shoulder blades. 24 Oct 2019*: The pet owner reports seeing an unknown amount of fleas. The dog does have access to an open yard, with trees and brush on the property. No treatments have been provided at home. The dog's current condition is ongoing. There are also 4 cats in the household, who are on FRONTLINE PLUS, with a report of fleas (see Case 19US063219). No further medical information expected.
24-Oct-2019	UAE; 19US063291; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Oct-2019*	24-Oct-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the pet owner reported the following event for 1 cat of unknown signalment. 10 Oct 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (S40606AW) to the skin between the shoulder blades for the first time after noticing an unknown species of tick on the pet. 24 Oct 2019: The owner reports removing 4 engorged live attached ticks from the cat. There is also a dog in the home. The cat is indoor/ outdoor. The outdoor environment is unknown. No further medical information expected.
24-Oct-2019	UAE; 19US063300; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 44 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jul-2019*	01-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the owner reported the following event for a 44 pound dog (signalment unknown). *July 2019: The dog had fleas and started monthly applications of FRONTLINE PLUS DOG 23-44 LBS (FL) (R60316AL) topically to the skin between the shoulder blades. *Aug 2019: Another FL application was applied and the dog still had fleas. *Sept 2019: Another FL application was applied and the dog still had fleas. *Oct 2019: Another FL application was applied and the dog still had fleas. The dog continued to pick up fleas after each monthly application and the owner is removing around 12 each day. The dog is exposed to the outdoor environment daily for potty breaks and leisure time. The dog is bathed every 10 days with fleas shampoo and suffers from sensitive skin. There is one cat in the home who

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ED_005739D_00014391-00397

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											also has fleas, see case. No further information available.
24-Oct-2019	UAE; 19US063322; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 49 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Oct-2019	24-Oct-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the owner reported the following event for a canine weighing 49 pound (all other signalments unknown). 11 Oct 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, package unavailable) was applied between the shoulder blades. 24 Oct 2019: The owner started to notice fleas on the pet for the first time. The dog has been using the product year round since 2010* with no issue.The dog goes out in an open yard. There are 2 other dog in the home being treated and having no issue. No further medical information is expected.
23-Oct-2019	UAE; 19US063329; TN; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Apr-2019*	01-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the pet owner reported the following event for a 5 year old feline of unknown signalment. Unknown: The owner has applied FRONTLINE PLUS CAT at unknown intervals for an unknown amount of times. Apr 2019*: The owner bought a 6 pack and applied FRONTLINE PLUS CAT (Lot unknown) (package unavailable) by an unknown method at unknown intervals. May 2019 through Sep 2019*: The owner applied monthly doses. Fleas have been seen continuously since Apr 2019*. It is unknown if the owner has been noticing fleas off of the pet inside the home . It is unknown if the pet is bathed or if it has any skin issues. The environment is unknown. It is unknown if the pet has presented to the veterinarian. It is unknown if the pet is indoor/outdoor. There an unknown number of animals in the household. No further medical information expected.
24-Oct-2019	UAE; 19US063337; -; U.S.A	**Species:** Canine **Breed:** West Highland White **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 18 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Jun-2019	10-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the pet owner reported the following event for Bella, a 7 year old, 18 pound, female spayed West Highland Terrier. History: The owner applied FRONTLINE PLUS DOG 5-22 LBS seasonally between June through November. 3 Jun 2019: The owner applied FRONTLINE PLUS DOG 5-22 LBS (Lot unknown) (package unavailable) 1 vial topically between the shoulder blades for the first time this season. 3 Jul thorough 3 Sep 2019: Monthly doses were applied. 3 Oct 2019: The most recent dose is applied. 10 Oct 2019: Owner was seeing an increase in itching and gave a bath with flea shampoo. Dead fleas seen in bath. Veterinarian technician advised reapplying a dose because the bath washed it off. Fleas have not been seen continuously and owner has not seen any more fleas since the bath and no flea dirt is seen. The owner has not been noticing fleas off of the pet inside the home . The pet does not have any skin issues. The yard is fenced with grass and the pet goes on walks. The pet has not presented to the veterinarian. The pet is indoor/outdoor. There a total of 1 canine in the household. No further medical information expected.
18-Oct-2019	UAE; 19US063346; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE	06-Oct-2019*	07-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the pet owner reported the following event for four cats of unknown signalment. 6 Oct 2019: The patient got their dose of FRONTLINE PLUS CATS (lot unknown, reporter refused). Owner stated cats have used

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ED_005739D_00014391-00398

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					FRONTLINE for several years, but exact dates are unknown. It is unknown if cats had prior doses this year. It is unknown where the dose was applied on the animals 7 Oct 2019*: The owner noticed 2-6 ticks daily until this day. It is unknown if the ticks were all dead or alive. It is unknown if they were identified. Owner does try to remove ticks, but does not know if she got them all. The pets do go outside in a wooded area. It is unknown if they are showing any skin issues. It is unknown if ticks are being seen in the house or not. It is unknown if the cats are bathed. The patient's current condition is ongoing. There is a total of 4 felines in the household. Owner refused further inquiry, they were primarily wondering if FRONTLINE expired. No further medical information expected.
18-Oct-2019	UAE; 19US063354; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	11-Oct-2019*	17-Oct-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the pet owner reported the following event for a cat of unknown signalment. 11 Oct 2019*: The patient got their dose of FRONTLINE PLUS CATS(lot unknown, package unavailable). Fleas were not seen prior to the dose. It is unknown if the cat has ever had FRONTLINE before. It is unknown how it was applied. 17 Oct 2019*: The owner noticed fleas on the animal. It is unknown if the pet goes outside. It is unknown if the cat is having any skin issues. It is unknown if the cat is bathed. It is unknown if fleas are being seen in the home or on the owner. The owner did state the cat licked the FRONTLINE PLUS. The patient's current condition is ongoing. The total number of animals in the home is unknown. Owner primarily wanting to know if the licking of the FRONTLINE could have caused this issue, she refused further inquiry. No further medical information expected.
18-Oct-2019	UAE; 19US063356; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2017*	01-Jan-2017*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Oct 2019, the pet owner reported the following event for a dog of unknown signalment. 2017*: The patient got their dose of FRONTLINE PLUS DOG (Unsubstantiated)(lot unknown). It is unknown if the dog was on monthly FRONTLINE at this time. It is unknown how it was applied to the animal. 2017*: The owner saw 1 flea. It is unknown how often the animal goes outside, but they do. It is unknown if the animal was having any skin issues. It is unknown if they were bathed. It is unknown if the owner was seeing fleas in the house at this time or on her person. The patient's current condition is unknown. The total number of animals in the house is unknown. Reporter refused inquiry, she was primarily calling in to ask about using FRONTLINE PLUS and Seresto at the same time do deal with a current flea infestation. She stated the dog was not currently using FRONTLINE at the time of this new infestation. No further medical information expected.
24-Oct-2019	UAE; 19US063360; MN; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 70 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	15-Aug-2019*	16-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the pet owner reported the following event for an 8 year old, 70 pound*, canine of further unknown signalment. Unknown dates: Since 2011*, the canine has received one vial of FRONTLINE PLUS DOG 45-88 LBS (FL+) (lot unknown; package unavailable). One vial has since been applied topically between the shoulder blades on unknown dates via unknown frequency. 15 Aug 2019*: FL+ was applied for the first time this year and at the time of application, an unknown number of Deer ticks were seen on the dog.

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ED_005739D_00014391-00399

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					Unknown date: An unknown duration after FL+ was applied, the reporter was continually finding and removing an unknown number of Deer ticks on the dog. 15 Sep 2019*: A second vial of FL+ was applied at which time, an unknown number of Deer ticks were seen on the dog. Unknown date: An unknown duration after FL+ was applied, the reporter was continually finding and removing an unknown number of Deer ticks on the dog. 11 Oct 2019*: A third vial of FL+ was applied at which time, an unknown number of Deer ticks were seen on the dog. Unknown date: An unknown duration after FL+ was applied, the reporter was continually finding and removing an unknown number of Deer ticks on the dog. Presently, the dog's status is unknown. The reporter suspects he's removed approximately 300 Deer ticks from the dog since the Aug 2019 application. Of the ticks removed, an unknown quantity were attached and engorged. It could not be confirmed if he ever found any dead ticks on the dog following product use. Information regarding the external environment is unknown because the reporter declined providing additional information. There are no other animals in the home. No further medical information expected.
24-Oct-2019	UAE; 19US063365; MI; U.S.A	**Species:** Canine **Breed:** Beagle **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 37 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Oct-2019	24-Oct-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the pet owner reported the following event for Viva, a 37 pound, female spayed, 1 year old, Beagle. 16 Oct 2019: There were no ticks on the dog. The owner applied 1 vial of FRONTLINE PLUS DOG 23-44 LBS(S61602AX) in one area between the shoulder blades. This was not the first application of the year, the owner treats has been treating monthly for 1 year. 18 Oct 2019*: The pet owners took a trip to their cabin the woods where the dog was going out for potty breaks and recreation and for hikes. 24 Oct 2019: They have returned from the cabin and the owner found 1 engorged tick the size of a popcorn kernel on the dogs face. The owner believes the tick is a deer tick. The owner removed it and saved it in a zip lock bag. It is unknown how long the tick had been on the dog, the pet owner noticed it on 24 Oct 2019. The dog has not had an issue with ticks in the past. The dog has not had a bath or gone swimming. No further information.
24-Oct-2019	UAE; 19US063368; MA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019*	24-Oct-2019*	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the pet owner reported the following event for 1 dog of unknown signalment. 01 May 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown/ package unavailable) topically to an unknown location monthly for the first time. 01 Oct 2019*: A dose was applied. 24 Oct 2019" The owner reports removing live attached deer ticks from his dog. The dog is taken into the woods for extended periods of time with the owner for hunting. It is unknown if the dog received a bath. Ticks are being seen in the home and biting humans. No further medical information expected.

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ED_005739D_00014391-00400

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
24-Oct-2019	UAE; 19US063386; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	10-Oct-2019	11-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the pet owner reported the following event for a 15 pound feline of unknown signalment. 10 Oct 2019: The owner began seeing flea dirt. The owner applied FRONTLINE PLUS CAT (Lot unknown) (package unavailable by an unknown method for the first time. 11 Oct 2019*: The owner began seeing flea dirt and an unknown amount of fleas. The owner has not been noticing fleas off of the pet inside the home. It is unknown if the pet is bathed or if it has any skin issues. The yard is (fenced with grassy/wooded/bushes/wildlife present). The environment is unknown. It is unknown if the pet has presented to the veterinarian. The pet is indoor only. This is the only pet in the home. No further medical information expected.
24-Oct-2019	UAE; 19US063405; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jul-2019*	24-Oct-2019*	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Oct 2019, the owner reported the following event for a 10 pound cat (signalment unknown). *July 2019: The cat had fleas and started monthly applications of FRONTLINE PLUS (FL) (S40502AX) topically to the skin between the shoulder blades. *Aug 2019: Another FL application was applied and the cat still had fleas. *Sept 2019: Another FL application was applied and the cat still had fleas. *Oct 2019: Another FL application was applied and the cat still had fleas. The cat continued to pick up fleas after each monthly application and the owner is removing around 12 each day. The cat is indoor/outdoor and goes out daily. The cat is bathed with fleas shampoo to remove the fleas. The cat had a reaction after the first application, see case 19US063424. There is one dog in the home who also has fleas, see case 19US063300. No further information available.
25-Oct-2019	UAE; 19US063421; -; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Unknown Antibiotic; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Oct-2019*	18-Oct-2019*	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Oct 2019, the pet owner reported the following event for 1 feline, male, Domestic Longhair, all other signalments unknown. 15 May 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (S41003) to the skin between the shoulder blades monthly for the first time. 11 Oct 2019*: The pet started a course of unknown antibiotics for an unknown ailment. 15 Oct 2019*: The owner applied a dose. 18 Oct 2019*: The owner noticed 3 to 4 live fleas daily on the pet for the first time. 25 Oct 2019: The owner reports continuing to see 3 to 4 live fleas on the cat. The cat is being kept inside for an unknown time frame. There is one other cat in the home on the product. The cat is indoors/ outdoors. The pet has not received a bath. The owner reports during the change of seasons the cat gets dry skin on his back. No fleas have been seen in the home. No further medical information expected.
24-Oct-2019	UAE; 19US063424; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON	01-Jul-2019*	01-Jul-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 24 Oct 2019, the owner reported the following event for a 10 pound cat (signalment unknown). *July 2019: The cat had fleas and started monthly applications of FRONTLINE PLUS (FL) (S40502AX) topically to the skin between the shoulder blades for the first time. After the dose the cat hid for

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ED_005739D_00014391-00401

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown **Age:** - **Weight:** 10 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					days. Unknown date: The cat developed loss of appetite and lethargy. The cat recovered after 4 days. The cat also has fleas, see case 19US063405. No further information available.
21-Oct-2019	UAE; 19US063438; MI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 20.000 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Seresto Collar; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	22-Sep-2019	22-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Oct 2019, the pet owner reported the following event for Falco, a 4 year old 20 pound male neutered canine of unknown breed. 22 Sep 2019: The owner noticed a small amount of fleas on the pet. The owner bought a 3 pack and applied FRONTLINE PLUS DOG 23-44 LBS (S61009AL), 1 vial topically between the shoulder blades monthly. The dogs are treated seasonally from April through December. Sep 2019*: The pets were bathed twice in Dawn dish soap. Fleas have been seen continuously since 22 Sep 2019. The owner has not been noticing fleas off of the pet inside the home . It is unknown if the pets have any skin issues. The yard is fenced with grass. The pets has not presented to the veterinarian. The pets are indoor/outdoor. The pets also wear seresto collars. There a total of 3 canines, a litter of 4 week old puppies and 1 feline in the household. The feline is treated with FRONTLINE PLUS CAT, see case 19US062561. There was another cat that passed away on 19 Oct 2019, see case 19US062566. The other dog are treated with FRONTLINE PLUS DOG 89-132 LBS and fleas are being seen on these pets. See case 19US062576 and 19US062571. The puppies are not being treated and not live fleas have been seen. No further medical information expected.
25-Oct-2019	UAE; 19US063465; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 60 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Route not indicated / recommended)	04-Oct-2019	24-Oct-2019*	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Oct 2019, the owner reported the following event for a 60 pound female dog. 4 Oct 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, packaging unavailable) was given topically to the fur between the shoulder blades. *24 Oct 201: The owner noticed the dog biting herself and found one flea on her. The dog is exposed to grass outside and is not bath often only on occasion. The dog doesn't have dry skin and is treated monthly yearround. There are two treated cats in the home who isn't having a flea issue. No further information available.
25-Oct-2019	UAE; 19US063466; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown Shampoo; **Route:** Topical / Cutaneous	19-Oct-2019	20-Oct-2019	1 Day(s)	D-D	Suspected Adverse Event: On 25 Oct 2019, the pet owner reported the following event for a canine of unknown signalment. 18 Oct 2019: The animal was bathed with an unknown shampoo. 19 Oct 2019: The patient received a dose of FRONTLINE PLUS(Unsubstantiated)(lot and expiration unknown, reporter refused). It is unknown as to where it was applied. 20 Oct 2019: The patient began itching. The patient's current condition is unknown. The owner refused further inquiry, she primarily called to ask if she could shower the animal again because she believes it was the last shampoo that caused the itching not the FRONTLINE. No

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ED_005739D_00014391-00402

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					further medical information expected.
25-Oct-2019	UAE; 19US063479; -; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.30 Year(s) **Weight:** 95 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** AFOXOLANER 136 MG CHEWABLE TABLETS; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	16-Nov-2018	25-Oct-2019	11 Month(s) 1 Week(s)	D-C	Suspected Lack of Efficacy: On 25 Oct 2019, the clinic staff reported the following event for Lola, 1.3 year old, 95 pound, female, neutered, Large Crossbreed Mix. 1 Mar 2019*: The owner started the dog on NEXGARD (136mg) (Lot and Expiry unknown, Package unavailable) with a 6 pack purchased on this date. 1 Oct 2019*: A chew was administered. 25 Oct 2019: The dog was presented to the clinic for an annual, and a 4dx snap test was positive for Lyme. The dog is not showing any clinical symptoms and has no past history of Lyme vaccines. The dog has not started treatment, and the clinic plans to send out a Quant C6 test. The dog's current status is unknown. There is one other dog in the home on the same size dose. No further information available at this time. UPDATE 8 Nov 2019 per medical record received on 29 Oct 2019: 16 Nov 2018: A dose of FRONTLINE PLUS DOG (product unsubstantiated) was applied to the pet. 29 Mar 2019, 9 Aug 2019, and 24 Jul 2019: Twelve packs of NEXGARD were purchased for the dogs to share. 28 Oct 2019: A Quant C6 test revealed a result of 55 (0-30). The pet was treated with doxycycline. No further medical information expected.
25-Oct-2019	UAE; 19US063486; MI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 50.0 - 70.0 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	31-May-2019*	01-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Oct 2019, the pet owner reported the following event for a female Golden Retriever, and a canine of unknown signalment, 50.0 pounds to 70.0 pounds*. Unknown Date: The pet owner noticed fleas on the 2 dogs and in the home. Jul 2019*: The pet owner flea bombed the house. May 2019 through Aug 2019*: The pet owner applied 1 dose, per dog, of FRONTLINE PLUS DOG 45-88 LBS (lot unknown, Package Unavailable), in one spot, between the shoulder blades to the dogs. Unknown Dates: The pet owner treated the home and the dogs with Natural Care Flea and Tick spray. 1 Sep 2019*: The pet owner still sees fleas. The pet owner continues to see over 20 fleas on each dog, when using an electric flea comb. The dogs have access to 2 acres with no fencing. There are 3 cats in the home that go outside and are treated with an unknown flea treatment. An adverse reaction was reported for one of the dogs (See Case 19US063503). No further medical information expected.
25-Oct-2019	UAE; 19US063490; WA; U.S.A	**Species:** Canine **Breed:** Canine Crossbred **Sex:** M **Sex qualifier:** - **Age:** 1.00 Year(s) **Weight:** 30 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	02-Oct-2019	15-Oct-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 25 Oct 2019, the pet owner reported the following event for Elo, a 1 year old, 30 pound, male intacted crossbreed canine. 1 Oct 2019: The owner adopted the pet and did not noticed fleas on the pet. The pet was bathed prior to application. 2 Oct 2019: The owner bought a 3 pack and applied FRONTLINE PLUS DOG 23-44 LBS (S62307AW), 1 vial topically between the shoulder blades for the first time. 15 Oct 2019: The owner started seeing a few fleas and applied another dose. 22 Oct 2019: The owner continued to see fleas and applied

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ED_005739D_00014391-00403

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: No (Treatment / vaccination program not respected)					another dose. The owner has not seen fleas off of the pet inside the home . It is unknown if the pet has any issues but the pet is reacting to the flea bites with redness and itching. The yard is grassy and wooded. The pet is walked on a leash. The pet has not presented to the veterinarian. The pet is indoor/outdoor. There a total of 1 canine and 2 indoor only felines in the household. The other pets are treated with FRONTLINE PLUS CAT and no fleas are being seen on these pets. No further medical information expected
25-Oct-2019	UAE; 19US063503; MI; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 50.0 - 70.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-May-2019*	31-May-2019*	1 Day(s)	D-B	Suspected Adverse Event: On 25 Oct 2019, the pet owner reported the following event for a female Golden Retriever, 50.0 to 70.0 pounds*. All other signalment is unknown. Unknown Date: The pet owner applied FRONTLINE PLUS DOG 45-88 LBS (lot unknown, Package Unavailable), in one spot, between the shoulder blades. The dog experienced a seizure an unknown amount of time later that lasted approximately 5 minutes. The dog recovered an unknown amount of time after the event, that same date. The dog did not present to the veterinary clinic and the dog was not treated. The dog has a history of seizures after receiving unknown flea treatments. The dog has received FRONTLINE PLUS DOG 45-88 LBS for the first time from May 2019 through Aug 2019. Specific details are not known. There is another case regarding fleas reported by the pet owner (See Case 19US063486). No further medical information is expected.
25-Oct-2019	UAE; 19US063506; WI; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2013*	02-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Oct 2019, the owner reported the following event for a feline (all other signalments unknown). 2013*: The cat started on FRONTLINE PLUS on a monthly basis year round. 1 Oct 2019*: The most recent vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) was applied between the shoulder blades, by the pet owner. 2 Oct 2019*: The cat had fleas for the first time. It is unknown if the cat gets bathed. The owner is noticing flea activity in the household. It is unknown if cat is indoor only or not. There is 1 dog in the household using FRONTLINE PLUS as well with case 19US064490. No further medical information is expected.
25-Oct-2019	UAE; 19US063518; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 31 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Sep-2019	28-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Oct 2019, the owner reported the following event for a canine weighing 31 pounds (all other signalments unknown). 27 Sept 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (S62308AW) was applied between the shoulder blades. 28 Sept 2019*: The owner started to notice fleas on the pet for the first time. The dog has received the product seasonally since 2015*. The dog has access to an open yard. There are 2 cats in the home being treated and also having an issue (see case 19US064553). No further medical information is expected.
25-Oct-2019	UAE; 19US063520; RI; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	17-Oct-2019	25-Oct-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Oct 2019, the pet owner reported the following event for Alister, a 1 year old, 15 pound, male neutered, Domestic Shorthair. 17 Oct 2019: 1 vial of FRONTLINE PLUS CATS(lot and expiration

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ED_005739D_00014391-00404

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 15 lbs				12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					unknown, package unavailable) was applied to the cat in one area between the shoulder blades. The owner has been treating the cat since he was a kitten with FRONTLINE monthly with no problems. The cat is an indoor/outdoor cat. 25 Oct 2019: The owner removed 4-5 live ticks from the cats neck and head. 4 of the ticks were engorged 1 was not. The ticks were brown and black. The owner removed the ticks. It is unknown how long the ticks have been on the cat, the owner noticed them today. The owner has never seen ticks on the cat in the past. No further medical information is expected.
25-Oct-2019	UAE; 19US063532; MI; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 8.85 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Prednisolone; Proviable; Cosequin; **Route:** unknown **Was the product used ok?:** Unknown to Company	22-Oct-2019	22-Oct-2019	0 Day(s)	D-C	Suspected Adverse Event: On 25 Oct 2019, the clinic staff reported the following event for Beanie, a 14 year old (9 Jun 2005), 8.850 pound, spayed female, Domestic Shorthair. 22 Oct 2019: The patient received a FRONTLINE PLUS CATS (S41305AW), Prednisolone, Proviable, and Cosequin. Later that day The patient began experiencing lethargy and seemed to be in a weird mood. 25 Oct 2019: The patient presented to the veterinary clinic. The animal's temperature was taken and came up as 104.5 F. Treatments have not been started yet. The patient's current condition is unknown. The patient has a pertinent medical history of Irritable Bowel Disease for an unknown period of time. No further medical information expected. UPDATE 7 Nov 2019: Upon internal review, additional coding was entered for the clinical signs reported. No further medical information expected.
25-Oct-2019	UAE; 19US063543; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2019*	15-Jul-2019*	2 Week(s)	D-A	Suspected Adverse Event: On 25 Oct 2019, the owner reported the following event for a canine of unknown signalment. Unknown: The pet began received FRONTLINE PLUS 45-88 LBS (lot unknown) (package unavailable). Unknown: The pet passed away on an unknown date. Owner stated the pet passed away a few months ago. No further medical information expected.
25-Oct-2019	UAE; 19US063565; MD; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 9 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Sep-2019*	14-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 25 Oct 2019 a pet owner called to report the following event in Mandi, a 12 year old, 9 pound, spayed female, Chihuahua canine. 1 Jan 2014*: The dog began to recieve FRONTLINE PLUS 5-22LBS (L64814AL) in between it's shoulder blades monthly year round with the most recent dose being applied on 2 Oct 2019*. 14 Oct 2019*: The owner began to notice fleas on her dog. 22 Oct 2019: The pet owner bathed the dog in Dawn dish soap. 23 Oct 2019: The pet owner applied one dose of FRONTLINE PLUS. 25 Oct 2019: The pet owner continues to see fleas on the dog. There are no other animals in the home. The dog is leashed walk near the house only on a sidewalk near grass. The dog has access to an outdoor porch that she frequents. No further medical information expected.

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ED_005739D_00014391-00405

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
25-Oct-2019	UAE; 19US063566; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 13.00 Month(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	25-Oct-2019	25-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 25 Oct 2019, the pet owner reported the following event for a 13 month old*, male, feline of further unknown signalment. 25 Oct 2019: Shortly after applying unknown FRONTLINE PLUS (lot unknown; reporter refused) (product unsubstantiated) topically between the cat's shoulder blades, the feline licked some of the product off of his hair coat. In doing so, he made a face and shook his head. While making the report, the pet owner observed the feline continue to groom the product off of himself and exhibit the same symptoms. She could not further describe the face the cat made, but indicated it was atypical behavior. It's unknown if he's previously received this product. It's also unknown if any treatment has been given for the ongoing event. No further medical information expected.
25-Oct-2019	UAE; 19US063609; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jul-2019*	07-Jul-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Oct 2019, the pet owner reported the following event for 1 male dog of unknown signalment. 01 Jul 2019*: The owner applied FRONTLINE PLUS DOG (product unsubstantiated) in an unknown manner in an unknown location. It is unknown if this was the first use. 07 Jul 2019*: The dog was taken to the groomer's and came home with an unknown quantity of live fleas for the first time. No further information is known as reporting a lack of efficacy was not the intent of the call (see case 19US063604). No further medical information expected.
25-Oct-2019	UAE; 19US063624; KS; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Mar-2019*	21-Oct-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Oct 2019, the pet owner reported the following event for 2 cats with unknown signalment. Mar 2019*: The cats began receiving FRONTLINE PLUS CATS (S41004AW) for the first time this year. The product is given monthly in the warmer months. There were 3 vials purchased on an unknown date from a retail store. The product was applied directly on the skin between the shoulder blades. Fleas were seen prior to product application. 8 Oct 2019: The most recent date of application. 21 Oct 2019*: The owner noticed fleas. One of the cats was bathed with baby shampoo. 25 Oct 2019: The owner is still noticing an unknown amount of fleas. The cats are indoor/outdoor. It is unknown if the cats have presented to the veterinary clinic. It is unknown if treatments have been provided at home. The cats' current condition is ongoing. There is a total of 2 canines and 2 felines in the household. The dogs were previously wearing Seresto collars, applied on 1 Mar 2019*. There are 2 dogs in the home with fleas, see cases 19US064460 and 19US064464. No more information available at this time.
28-Oct-2019	UAE; 19US063648; -; U.S.A	**Species:** Canine **Breed:** Siberian Husky **Sex:** F **Sex qualifier:** Neutered **Age:** -	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	21-Sep-2019*	28-Oct-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, the pet owner reported the following event for a 65 pound, female spayed, Siberian Husky. All other signalments unknown. Sep 2019: The pet owner began treating the dog with FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown, package unavailable) in one area between the shoulder blades for the first time of the year. A 6 pack was purchased on Amazon. 21 Oct 2019: 1 vial was applied.

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ED_005739D_00014391-00406

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 65 lbs				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					28 Oct 2019: There are 5-10 fleas on the dog. There are no fleas in the home. The dog goes out for potty breaks and recreation in the yard. There are no other pets in the home. The dog has not had a bath recently or gone swimming. No further information.
28-Oct-2019	UAE; 19US063650; PA; U.S.A	**Species:** Canine **Breed:** Bichon Frise **Sex:** F **Sex qualifier:** - **Age:** 7.00 Month(s) **Weight:** 14 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Oct-2019	18-Oct-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for Zoey, a 7 month old (born 14 Mar 2019) 14 pound female intact Bichon/Frise mix. 28 Jul 2019*: The pet owner started using monthly dose of FRONTLINE PLUS DOG 5-22 LBS (S62106). 2 Oct 2019: Last dose given. 10 Oct 2019*: The pet owner started to find flea dirt on the dog. 18 Oct 2019: The pet owner found a few fleas on the dog. The dog goes outside for short breaks. There are no other dogs in the home and there are no fleas in the home. The dog is bathed about once pet month with an unknown shampoo. The dog was bathed with dawn after seeing the fleas. No further medical information expected.
28-Oct-2019	UAE; 19US063651; ME; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Jul-2019*	28-Oct-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for Oliver, a male feline, of further unknown signalment. Jul 2019*: The pet owner noticed ticks on the cat. 22 Jul 2019*: The pet owner applied 1 dose of FRONTLINE PLUS CATS (S40502AX), in an unknown location, on the cat. This dose was a week late, as the pet owner always applies on the 15th of every month. 15 Aug 2019 through 15 Oct 2019: The pet owner applied FRONTLINE PLUS CATS to the cat. Unknown dates: The pet owner continues to see 1 to 3 daily ticks on the cat. The pet owner has not seen any ticks in the home. The cat is outside most of the time with access to a lawn and woods. It is unknown if the cat has been treated. The cat has previously received FRONTLINE PLUS CATS monthly, year round, since 2018. There are no other pets in the home. No further medical information expected.
28-Oct-2019	UAE; 19US063654; MI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Sep-2019*	01-Oct-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for a canine of unknown signalment. 1 Oct 2014*: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (T606131L) monthly during summer season. The product was applied directly on the skin between the shoulder blades. No fleas seen prior to product application. 18 Sep 2019*: The pet owner applied the product to the dog. 1 Oct 2019*: The owner noticed a small amount of fleas. The dog has access to a fenced in yard, no trees or brush on the property. No treatments have been provided at home. The dog's current condition is ongoing. There is one other dog and an unknown amount of cats in the household. All pets are treated with FRONTLINE PLUS, the cats have no fleas, but the other dog has been scratching (see case 19US063660). No further medical information expected.
28-Oct-2019	UAE; 19US063660; MI; U.S.A	**Species:** Canine **Breed:** Canine (unknown)	1	1	0	**Product used:** FIPRONIL 10%/S	18-Sep-2019*	01-Oct-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim and Adverse Event: On 28 Oct 2019, the pet owner reported the following event for a canine of unknown signalment.

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ED_005739D_00014391-00407

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					1 Oct 2014*: The dog began receiving FRONTLINE PLUS DOG 23-44 LBS (F62307AW) monthly during summer season. The product was applied directly on the skin between the shoulder blades. No fleas seen prior to product application. 18 Sep 2019*: The pet owner applied the product to the dog. 1 Oct 2019*: The owner noticed the dog scratching, no fleas have been seen. The dog has access to a fended in yard, no trees or brush on the property. No treatments have been provided at home. The dog's current condition is ongoing. There is one other dog and an unknown amount of cats in the household. All pets are treated with FRONTLINE PLUS, the cats have no fleas, but the other dog has fleas (see case 19US063654). No further medical information expected.
28-Oct-2019	UAE; 19US063662; WI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 16.8 - 17.2 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown shampoo; **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	15-Oct-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the veterinarian reported the following event for approximately two canines of unknown signalment. Unknown dates: An unknown duration after unknown FRONTLINE PLUS (lot unknown; package unavailable) was administered via unknown route and location, the pet owner would find an unknown number of ticks on the dogs. The species and status of the ticks when they were found are unknown. Presently, the dogs' statuses are unknown. At least one of the dogs has a history of reaction to unknown pyrethrins. The reporter was not calling to report an event, but simply called to ask questions. No further medical information expected. UPDATE 28 Oct 2019: Per the veterinarian, the dogs weigh 16.8 pound and 17.2 pounds. Unknown dates: The patients began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (lot unknown; package unavailable) applied topically between the shoulder blades, monthly. The frequency and dates of application remain unknown. On unknown dates, an unknown duration before or after FL+ application, the pet owner bathed the dogs with an unknown (dog) shampoo. The pet owner has not bathed the dogs moe than once weekly and waits at least 48 hours before or after FL+ application before bathing. An unknown duration after FL+ application, on unknown dates, the pet owner was finding a large number of attached ticks on the dogs. The reporter could not confirm the species of ticks nor did she have any further details regarding the condition of said ticks. On an unknown recent date, one of the dogs also tested positive for Lyme disease and Anaplasmosis via unknown test; however the other dog tested negative for tick borne diseases. UPDATE 29 Oct 2019: Per a phone conversation with the veterinarian on 28 Oct 2019, the patient's have a history of seizures after application of an unknown permethrin product on an unknown date. No further medical information expected.
03-Dec-2019	UAE; 19US063664; IL; U.S.A	**Species:** Canine **Breed:** Leonberger **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 105 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Wondercide Flea	24-Sep-2019*	03-Dec-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for 1 105 pound, male Leonberger, all other signalment unknown. 24 Aug 2019*: The owner applied Wondercide Flea Spray after noticing 6 to 8 live fleas on the pet. 24 Sep 2019*: The owner applied the contents of 1 vial of FRONTLINE PLUS DOG 89-132 LBS (S60621AR) to the skin multiple spots down the spine for the first time after continuing to see 6 to 8 live fleas on the pet per day.

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ED_005739D_00014391-00408

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Spray; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					24 Oct 2019: The dog was bathed with Wondercide Flea Shampoo. A dose was applied. 28 Oct 2019: The owner finding 3 to 4 live fleas on the pet per day. There are also 2 outdoor barn cats on FRONTLINE PLUS CAT (19US063688). The dog is outside for short periods. The owner mentioned the neighbor's having a known flea biomass. The owner reports vacuuming and washing the dog's bedding daily. No fleas have been noticed in the home. No further medical information expected. UPDATE 08 Nov 2019: Case changed to an inquiry due to preexisting fleas and less than 3 months administered. UPDATE 3 Dec 2019: Per the Pet owner, 20 Nov 2019: The owner continued to notice an unknown amount of fleas on the dog and applied FRONTLINE PLUS to the pet. 3 Dec 2019: The owner noticed the pet scratching and took one live flea off the pet. The owner does not see fleas in the home. There are no fleas seen on the cats in the home. No further medical information expected.
28-Oct-2019	UAE; 19US063676; FL; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 30 - 42 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dog Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Oct-2019	10-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim and Adverse Event Claim : On 28 Oct 2019, the pet owner reported the following event for Jake, a 8 year old, 30 pound male canine and Molly a 6 year old, 42 pound female canine of unknown further signalments. Unknown: The pets were previously treated with Comfortis with no adverse events and no fleas noted. 8 Oct 2019: The owner noticed a moderate amount of fleas on the pets and bathed the pets with dog shampoo. 9 Oct 2019: The owner bought a 6 pack and applied FRONTLINE PLUS DOG 23-44 LBS (S60713AX), 1 vial per animal topically between the shoulder blades for the first time. 10 Oct 2019: The owner noticed itching for both pets. The owner has seen fleas continuously during this time. The owner has not been noticing fleas off of the pets inside the home . Jake has known skin allergies. Molly does not have skin issues. The yard is fenced with grass and wildlife present. The pets have not presented to the veterinarian. The pets are outdoor only. There are a total of 2 canines in the household. No further medical information expected.
28-Oct-2019	UAE; 19US063685; NY; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	05-Oct-2019*	27-Oct-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the owner reported the following event for a female cat (signalment unknown). *5 Oct 2019: One vial of FRONTLINE PLUS CATS (FL) (lot unknown, reporter not queried) was applied topically. *Unknown date: The vet found one flea on the cat and given a shot to calm her skin. 27 Oct 2019: The cat was full of fleas. The cat is indoor and outdoor (environment unknown) and is treated monthly for an unknown lenght of time. There are 2 untreated outdoor cats. No further information available.
02-Dec-2019	UAE; 19US063697; MD; U.S.A	**Species:** Feline **Breed:** Persian (No Further Description)	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE	30-Aug-2019	14-Nov-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the owner reported the following event for 3, 9-15 years old, 9- 11 pounds, neutered male, Persians. Unknown date: Fleas were seen on the cats.

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ED_005739D_00014391-00409

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 9 - 11 lbs				12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					30 Aug 2019: The first dose of FRONTLINE PLUS was applied. 12 Oct 2019: The most recent vial of FRONTLINE PLUS CATS (S41411AW) was applied between the shoulder blades, by the pet owner. 13 Oct 2019*: The cats had fleas. The cats were bathed in an unknown pet approved shampoo. The owner is not noticing any flea activity in the household. The cats are indoor only cats. There is 1 dog in the household using FRONTLINE as well but is not having any issues with fleas. No further medical information is expected. UPDATE 08 Nov 2019: Case changed to an inquiry due to preexisting fleas and less than 3 months administered. UPDATE 2 Dec 2019: 14 Nov 2019: Owner applied the monthly dose. Owner is seeing a slight increase in the number of fleas. No further medical information expected.
23-Oct-2019	UAE; 19US063709; NC; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Apr-2009*	01-Apr-2019*	0 Day(s)	D-A	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 23 Oct 2019, the owner reported the following event via email for Hannah, Retriever (Golden) (all other signalments unknown). 2009*: The dog was using FRONTLINE PLUS on a monthly basis. It is unknown if it was year round use. Apr 2019: The most recent vial of FRONTLINE PLUS DOG (lot unknown, package unavailable, product unsubstantiated) was applied between the shoulder blades, by the pet owner. The dog had fleas. Apr 2019: The passed away. The dog had mast cell, but the owner believed that the product contributed to the death of the dog. No further medical information is expected. UPDATE 12 Nov 2019: There is 1 cat in the household using FRONTLINE PLUS as well with case 19US066542. No further information is expected. UPDATE 25 NOV 2019: Corrected case to serious.
28-Oct-2019	UAE; 19US063710; -; U.S.A	**Species:** Canine **Breed:** American Bully **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 80 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	03-Oct-2019	05-Oct-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for Buddy, a 3 year old, 80 pound, male neutered American Bulldog Labrador retriever cross . 3 Oct 2019: The owner bought a 3 pack and applied FRONTLINE PLUS DOG 89-132 LBS (656615), 1 vial topically between the shoulder blades for the first time. 5 Oct 2019: The owner noticed a moderate amount of fleas on the pet. Fleas have been seen continuously since 5 Oct 2019. The owner has not been noticing fleas off of the pet inside the home . The pet is not bathed and does not have any skin issues. The yard is fenced with grass and wildlife present. The pet has not presented to the veterinarian. The pet is indoor/outdoor. There a total of 1 canine and 2 felines in the household. The other pets are treated with FRONTLINE PLUS CAT and fleas are being seen on these pets. See case 19US063726. No further medical information expected.
28-Oct-2019	UAE; 19US063713; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** -	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other	07-Oct-2019*	28-Oct-2019*	3 Week(s)	D-D	Suspected Adverse Event: On 28 Oct 2019, the pet owner reported the following event for a Feline of unknown signalment. 7 Oct 2019*: The patient got their dose of FRONTLINE PLUS CATS (Unsubstantiated)(lot unknown, reporter refused). It is unknown how long the animals were on FRONTLINE, or if fleas were seen before this last dose. It is unknown how it was applied. 28 Oct 2019*: The owner noticed the animals seem to be itching

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ED_005739D_00014391-00410

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products **Route:** unknown **Was the product used ok?:** Unknown to Company					again, and she believes it is due to the fleas. It is unknown if fleas were directly seen since giving FRONTLINE. It is unknown if the pet goes outside or how often. One of the animals is having a small amount of hairloss at the application site, but no irritation seen. It is unknown if the animal gets bathed. It is also unknown if any fleas have been seen in the home or on the owner. The patient's current condition is ongoing. The Total number of animals in the house is unknown. Owner was primarily calling to ask if she should give another dose before 30 days and if she could bathe them with an Unknown Flea and Tick Shampoo. She refused further inquiry. No further medical information expected.
28-Oct-2019	UAE; 19US063718; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Oct-2017*	28-Oct-2019	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for a female feline of further unknown signalment. 5 Oct 2019*: The pet owner applied a dose of FRONTLINE PLUS CATS (lot unknown, not queried). 28 Oct 2019: The pet owner found fleas and ticks on the cat. The cat goes outside. Ticks were dying the caller reported. Pet has been on FRONTLINE for an unknown number of years. No further medical information expected.
28-Oct-2019	UAE; 19US063726; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Neutered **Age:** 8.00 Month(s) **Weight:** 11.5 - 20 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Oct-2019	05-Oct-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for Pumpkin, a 8 year old, 20 pound, female spayed feline of unknown breed and Kitten an 8 month old 11.5 pound male neutered feline of unknown breed. 3 Oct 2019: The owner bought a 3 pack and applied FRONTLINE PLUS CAT (653314) (invaild), 1 vial topically between the shoulder blades for the first time. 5 Oct 2019: The owner noticed a moderate amount of fleas on the pets. Fleas have been seen continuously since 5 Oct 2019. The owner has not been noticing fleas off of the pets inside the home. The pets are not bathed and do not have any skin issues. The pets have not presented to the veterinarian. The pets are indoor only. There a total of 1 canine and 2 felines in the household. The other pet is treated with FRONTLINE PLUS DOG 89-132 LBS and fleas are being seen on these pets. See case 19US063710. No further medical information expected.
28-Oct-2019	UAE; 19US063729; NJ; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 60 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Oct-2019	27-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On 28 Oct 2019, the owner reported the following event for an unknown female, 60 pound, Golden Retriever, all other signalment unknown. 27 Oct 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (unknown lot, package unavailable) was applied topically in one location in-between the shoulder blades by the pet owner. The owner noticed the dog rubbing her back on the carpet and having loose and mucosal stool. The dog was not presented to the clinic and the owner has not given any treatment. 28 Oct 2019: The symptoms have stopped. The pet has used FRONTLINE since Nov 2018. No further information is expected.

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ED_005739D_00014391-00411

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											PRODUCT QUALITY: On 28 Oct 2019, as reported by the owner the following issue with FRONTLINE DOG 45-88 LBS (Lot Unknown) out of an unknown amount purchased. The owner noticed a strong order from the product that has not been noticed before since using the product for years. The owner will not be returning the product. No further information.
28-Oct-2019	UAE; 19US063754; IL; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 15.9 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** IMRAB 1 TF - 1905.27; Depo-Medrol; dexamethasone; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019*	25-Oct-2019*	24 Day(s)	D-D	Suspected Adverse Event and Suspected Lack of Efficacy Claim : On 28 Oct 2019, the veterinarian reported the following event for Eddie, a 5 year old (born on unknown date in 2014), 15.9 pound, neutered male, Domestic Shorthair. Unknown date: The patient picked up an unknown number of fleas. 1 Oct 2019: The patient was seen by a colleague for the ongoing flea issue. He was treated with 20 mg of Depo-Medrol, IM. Unknown date: Unknown FRONTLINE PLUS (lot unknown; package unavailable) was applied. The dose, route, and location of unknown FRONTLINE PLUS administration is unknown. It's also unknown if fleas were seen at the time of product application. 25 Oct 2019: Eddie was pre-treated with 2 mg of dexamethasone, SC, given by the reporter's colleague. At least fifteen minutes following pre-treatment, Eddie was vaccinated by said colleague with IMRAB 1 TF (22096, 6 Mar 2021), 1 mL, SC, in the right hind leg. It's unknown if the feline has previously received IMRAB 1 TF and at the time of vaccination, the reporter stated Eddie was still battling fleas and was fractious; however, he did not specify if fleas were present or what the specific flea issue was. 26 Oct 2019: The patient became emetic and vomitus consisted mostly of food. He experienced no diarrhea and maintained a normal appetite. 28 Oct 2019: The feline presented to the reporter for evaluation. His physical exam was WNL except for the presence of flea dirt. Treatment consisted of Cerenia. The reporter has a medium level of suspicion that IMRAB 1 TF caused the event and the cat's status post-treatment is unknown. No further medical information expected.
28-Oct-2019	UAE; 19US063758; -; U.S.A	**Species:** Canine **Breed:** Rat Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 65 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019*	28-Oct-2019	27 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for a male 65 pound Rat Terrier mix. 1 Oct 2019*: The pet owner applied a dose of FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown, package unavailable). 28 Oct 2019: The pet owner found fleas on the dog. The dog goes outside where there are neighbor dogs. There are 4 cats in the home and there are foster cats who come and go. The cats are on an unknown treatment and it is unknown if they have fleas. There are no fleas in the home. The dog has been receiving FRONTLINE for an unknown number of years, unknown if it is year round. No further medical information expected.
28-Oct-2019	UAE; 19US063763; NC; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Mixed **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical /	07-Oct-2019*	28-Oct-2019	3 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for 3 mixed unknown Feline. All other signalments unknown. There was 1 flea seen on the cats who are indoor only. The cats have not had a flea treatment in 3-4 months. 7 Oct 2019: 1 vial of FRONTLINE PLUS CATS(lot and expiration unknown, package unavailable) were applied to the cats for the very first time in one area between the shoulder blades. 28 Oct 2019: The owner is seeing 1-5 fleas on the cats.

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ED_005739D_00014391-00412

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous **Was the product used ok?:** Yes					There are fleas in the home. The cats have not had a bath recently. No further information. UPDATE 6 Jan 2020: Per the pet owner, 8 Nov 2019 and 10 Dec 2019: The pet owner continued to notice fleas on the pets and applied FRONTLINE PLUS CATS. 6 Jan 2020: The owner continues to notice 1 to 2 fleas on the pets. The pets are indoor only and have no access to outdoor. There are no other pets in the home. the condition of the pets is unknown. No further medical information expected.
28-Oct-2019	UAE; 19US063766; MO; U.S.A	**Species:** Canine **Breed:** Spaniel (Brittany) **Sex:** M **Sex qualifier:** - **Age:** 14.00 Year(s) **Weight:** 28 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Oct-2019	26-Oct-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for Bubba, a 14 year old, 38 pound, male intacted Spaniel (Brittany). The owner applied FRONTLINE PLUS DOG 23-44 LBS (Lot unknown) (package unavailable), 1 vial topically between the shoulder blades monthly for many years. 25 Oct 2019: The most recent dose is applied. 26 Oct 2019*: The owner noticed a small amount of fleas on the pet. 28 Oct 2019: Owner noticed an increase in the amount of fleas and the pet's itching. The owner has not been noticing fleas off of the pet inside the home. The pet was not bathed recently and does not have any skin issues. The yard is fenced with grass and wildlife present. The pet has not presented to the veterinarian. The pet is indoor/outdoor. There a total of 1 canine and 3 felines in the household. The other pets are treated with FRONTLINE PLUS CAT and fleas are not seen on these pets. One of the cats is indoor/outdoor. The other 2 are indoor only. No further medical information expected.
28-Oct-2019	UAE; 19US063768; -; U.S.A	**Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Oct-2019*	28-Oct-2019	27 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for 1 female Toy Poodle, all other signalments unknown. 01 Jan 2017*: The owner applied the contents of 1 vial FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown/ package unavailable) topically in an unknown location monthly for the first time. 01 Oct 2019*: The owner applied a dose. 28 Oct 2019: The owner found 2 live fleas on the dog after being outside. The pet is going to the grooming salon in 2 days, it is unknown what shampoo is used. All other factors unknown as the intent of the call was not to report a lack of efficacy. No further medical information expected.
28-Oct-2019	UAE; 19US063778; NC; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** X **Sex qualifier:** Mixed **Age:** 4.00 Year(s) **Weight:** 65 - 85 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	12-Sep-2019	10-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019 the owner reported the following event for Sophie, 5 year old*, 80 pound*, spayed female, German Shepherd Dog and Maximus, a 4 year old*, 65 pound*, intact male, German Shepherd Dog. 11 Sep 2019*: The owner brought the pets to the veterinarian for scratching, per the clinic staff no fleas or flea dirt seen on the pets. 12 Sep 2019: The owner applied one vial of FRONTLINE PLUS DOG 45-88 LBS (T60101AX) topically between the shoulder blades for the first time. 10 Oct 2019*: The owner noticed an unknown amount of fleas on the pet and bathed them with an unknown pet shampoo. 12 Oct 2019: The pets continue to scratch. The owner noticed an unknown amount of fleas on the pets. The owner applied FRONTLINE PLUS to the pets.

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ED_005739D_00014391-00413

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											28 Oct 2019: The owner continues to notice fleas on the pet and in the home. The pets have access outside to a grass yard, where stray cats are present. There are no other pets in the home. The pets were in good health prior to the application and have no history of reactions. No further medical information expected. UPDATE 21 Nov 2019: The most recent application of the FRONTLINE PLUS was 2 weeks ago. The owner stated that fleas are still on the dogs and the amount has been consistent. No further medical information is expected.
28-Oct-2019	UAE; 19US063799; -; U.S.A	**Species:** Canine **Breed:** Spaniel (Cocker) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Capstar; FIPRONIL 9.8% / S-METHOPRENE 8.8% / PYRIPROXYFEN 0.25% TOPICAL SOLUTION; **Route:** Topical and Opthalmic **Was the product used ok?:** Unknown to Company	20-Oct-2019	21-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for a female Spaniel (Cocker) of unknown signalment. Unknown Date: Owner started applying FRONTLINE GOLD 5-22 LBS (lot unknown) (package unavailable), monthly for an unknown amount of time. The owner has not seen fleas during those times. 20 Aug 2019*: The owner applied the FRONTLINE GOLD monthly dose. Aug 2019*: The owner noticed a small amount of fleas on the pet. 20 Sep 2019*: The owner applied the monthly FRONTLINE GOLD dose. 1 Oct 2019* The owner is seeing a increase in the number of fleas. 16 Oct thorough the 21 Oct 2019: The owner gave Capstar orally once a day. 20 Oct 2019: The owner applied FRONTLINE PLUS 5-22 LBS (Lot unknown) (package unavailable), topically at an unknown dose and by an unknown method for the first time this year. Owner ordered FRONTLINE GOLD but was sent FRONTLINE PLUS. 21 Oct 2019: The owner is seeing a decreased amount of fleas, about 2-5. Fleas have been seen continuously since Aug 2019. The owner has been noticing fleas off the pet inside the home . The pet is not bathed and does not have any skin issues. The yard is wooded with wildlife present. The pet has not presented to the veterinarian. The pet is indoor/outdoor. There a total of 2 canines in the household. The other pet is treated with FRONTLINE PLUS 89-132 LBS and fleas are not being seen. No further medical information expected.
28-Oct-2019	UAE; 19US063804; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)	01-Sep-2019*	01-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the owner reported the following event for 2 dogs weighing 8 and 9 pounds (other signalment unknown). *1 Sept 2019: The owner applied FRONTLINE PLUS DOG 5-22 LBS (FL) (R60830) topically to the skin between the shoulder blades for the first time. *Unknown date: The dogs picked up fleas. *1 Oct 2019: The dogs received a half vial of FL and still continued to pick up fleas. There isn't any fleas in the home and the pet's outdoor environment is unknown. No further information available.
28-Oct-2019	UAE; 19US063807; PA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	09-Oct-2019	28-Oct-2019*	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for Shadow, a 2 year old, 9 pound, spayed female, Domestic Longhair. 1 Oct 2017*: The cat began receiving FRONTLINE PLUS CATS

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ED_005739D_00014391-00414

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 9 lbs				12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					(F40503AX) monthly year round. The product was applied directly on the skin between the shoulder blades. 9 Oct 2019: The most recent date of application. 28 Oct 2019*: The owner found four ticks on the cat. The cat does go outside to an unknown area. No treatments have been provided at home. The cat's current condition is ongoing. This is the only pet in the household. No further medical information expected.
28-Oct-2019	UAE; 19US063819; MA; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 8 lbs	2	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	14-Oct-2019*	14-Oct-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for a 7 year old, 8 pound, female Yorkshire terrier of unknown further signalment. History: The pet has received FRONTLINE PLUS monthly since she was a baby. 1 Oct 2019: The owner bought a 6 pack and applied FRONTLINE PLUS 5-22 LBS (Lot unknown) (package unavailable) 1 vial topically between the shoulder blades monthly. 14 Oct 2019*: The owner notice the pet itching more and saw a small amount of fleas. Owner applied FRONTLINE SPRAY topically, an unknown amount of pumps. 20 Oct 2019*: The owner bathed the pet in Dawn dish soap. 21 Oct 2019*: The owner reapplied FRONTLINE SPRAY topically, an unknown amount of pumps. 28 Oct 2019: Owner continues to see a small amount of fleas. The owner has not been noticing fleas off of the pet inside the home. The pet does not have any previous skin issues. The yard is grass and wooded with wildlife present. The pet has presented to the veterinarian. The veterinarian diagnosed flea allergy dermatitis and prescribed unknown oral medications. The pet is indoor/outdoor. There are a total of 2 canines in the household. The other pet are treated with FRONTLINE PLUS DOG and fleas are not seen. No further medical information expected.
28-Oct-2019	UAE; 19US063820; WA; U.S.A	**Species:** Canine **Breed:** Spaniel (English Springer) **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 48 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn Dish soap; vinegar; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)	06-Jan-2017*	01-Oct-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019 the owner reported the following event for Dagney, a 11 year old*, 48 pound*, spayed female, English Springer Spaniel. 6 Jan 2017* through 6 Sep 2019: The owner applied one vial of FRONTLINE PLUS DOG 23-44 LBS (R62420BL) topically between the shoulder blades monthly, year round. 1 Oct 2019*: The owner noticed an unknown amount of fleas on the pet. 6 Oct 2019: The owner continued to notice fleas on the pet and bathed the pet in Vinegar and Dawn dish soap. The owners wife uses a hair dryer to dry pet and applied FRONTLINE PLUS to the pet. 25 Oct 2019: The owner continues to notice fleas on the pet and bathes the pet in Dawn dish soap and vinegar, and dried the pet with a hair dryer. 27 Oct 2019: The owner continues to notice fleas on the pet and bathes the pet in Dawn dish soap and vinegar, and dried the pet with a hair dryer. 28 Oct 2019: The owner continues to notice a large amount of fleas on the pet. The pet has access to a Christmas tree farm, where urban wildlife is present. There are no other pets in the home. the pet is in good health and has no history of reactions. The owner does not see fleas in the home. No further medical information expected.

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ED_005739D_00014391-00415

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
28-Oct-2019	UAE; 19US063827; WI; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 11.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Sep-2019	27-Oct-2019	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for Ollie, a 6 year old, 11.0 pound*, neutered male feline. 7 Sep 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S40606AW), in one spot, between the shoulder blades to the cat. Unknown date: The pet owner noticed an engorged tick on the cat, which she removed. 7 Oct 2019: The most recent dose was applied to the cat. 27 Oct 2019: The pet owner again noticed an engorged tick on the cat, which she removed. It is unknown if the pet owner has found more ticks on the cat. The cat goes outside with access to a wooded area. The cat is in good health and has received FRONTLINE PLUS CATS monthly, year round since 2017 with no issues. There are two dogs in the home that are received NEXGARD and experience no issues. No further medical information expected. UPDATE 8 Nov 2019: Corrected outcome on patient screen to recovered. No further medical information expected.
27-Oct-2019	UAE; 19US063838; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Month(s) **Weight:** 4 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	27-Oct-2019	27-Oct-2019	0 Day(s)	D-C	Suspected Adverse Event: On 27 Oct 2019, the following event was reported to Safety Call International (SCI) by the owner for Wednesday, a 4 month old*, 4 pound*, spayed female, Domestic Shorthair. 27 Oct 2019: The owner applied an unknown amount of FRONTLINE PLUS CATS (lot unknown, package unavailable) topically on the shoulder blades of the pet. It is unknown if this is the first application of the product. Approximately 30 minutes after the application the pet started puffing and drooling. It is unknown if the pet licked the application site. Per the owner the pet may have licked her foot after scratching the application site. The pet was bathed with Palmolive dish detergent. The owner offered food and water, it is unknown if the pet recovered. The pet was in good health and has no history of reactions. No further medical information expected. UPDATE 1 Nov 2019: Multiple attempts have been made to follow up on the missing information. To date, the information has not been received. No further medical information expected.
28-Oct-2019	UAE; 19US063850; NY; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Oct-2019	28-Oct-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for 1 feline of unknown signalment. 06 May 2019*: The owner applied the contents of 1 vial FRONTLINE PLUS CATS (T40401AW, Feb 2022) to the skin between the shoulder blades monthly for the first time. Aug-Sep 2019: No dose was given. 06 Oct 2019: The owner applied a dose. 28 Oct 2019: The owner reports removing alive attached unknown species of ticks from the pet daily. There are 2 other cats in the home on FRONTLINE PLUS CATS with no ticks found. The cats are indoor/ outdoor. No prior skin conditions were reported. The owner has not bathed the cat. No further medical information expected.
28-Oct-2019	UAE; 19US063879; NC; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products**	19-Jan-2019*	28-Oct-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for a 14 year old*, 19 pound, male neutered, Feline (unknown). The owner treats the cats with FRONTLINE PLUS CATS (S41003AW) monthly and year round for an unknown number of years. The cat has had a treatment monthly since Jan. 2019.

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ED_005739D_00014391-00416

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 14.00 Year(s) **Weight:** 19 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					There were no fleas present on the cat. 19 Oct 2019: 1 vial was applied to the cat in one are between the shoulder blades. 28 Oct 2019: The cat presented to the veterinary clinic for vaccines and the technichians discovered a large amount of fleas on the cat. The cat spends a lot of time outside laying around the house. He is not very active and never leaves the front yard. There are no fleas seen in the home. The cat has not had a bath recently or gotten wet. No further medical information is expected.
28-Oct-2019	UAE; 19US063899; WI; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 13 - 14 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-Sep-2019*	22-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the pet owner reported the following event for Mittens, a 13.0 to 14.0 pound, neutered male Domestic Shorthair feline. 21 Sep 2019*: The pet owner applied one dose of FRONTLINE PLUS CATS (S41103AW), in one spot, between the shoulder blades to the cat. No fleas were noticed prior to this application. 22 Sep 2019*: The pet owner noticed fleas on the cat and in the home. The pet owner's wife was getting bitten by fleas. 21 Oct 2019: The most recent dose was applied. 22 Oct 2019*: The pet owner continues to see approximately 24 fleas at a time on the cat. The cat goes outside in a yard for potty breaks only. The cat has received FRONTLINE PLUS CATS, monthly, year round, previously with no issues since an unknown date. The pet owners have treated the home with an unknown flea spray at an unknown time. There are no other pets in the home. No further medical information expected.
28-Oct-2019	UAE; 19US063904; CA; U.S.A	**Species:** Feline **Breed:** Maine Coon Cat **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 18 - 20 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Oct-2019	27-Oct-2019*	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Oct 2019, the owner reported the following event for 2 Maine Coon felines weighing 18 and 20 pounds (all other signalments unknown). 11 Oct 2019: One vial of FRONTLINE PLUS CATS (S40601RX) was applied between the shoulder blades. 27 Oct 2019: The pet presented to the clinic with intense itching. The veterinarian found a large number of fleas. The owner went home and checked the other cat who also had a large number of fleas. 28 Oct 2019: The issue is still ongoing. The cats have received the product monthly since 11 Aug 2019 with no issue. No further medical information is expected.
28-Oct-2019	UAE; 19US063913; NE; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 7 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Oct-2019	28-Oct-2019	1 Day(s)	D-D	Suspected Adverse Event: On 28 Oct 2019, the clinic reported the following event for a 7 pounds, feline (all other signalments unknown). 27 Oct 2019: One vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) was applied between the shoulder blades, by the pet owner. 28 Oct 2019: The cat had neurological symptoms, the eyes had nystagmus, the product has a strong unpleasant smell and the cat could not stand up. The cat present to clinic. No further medical information is expected. UPDATE 4 Nov 2019: Product Quality: On 28 Oct 2019, the clinic staff reported the following issue with a single dose of FRONTLINE PLUS CATS (lot unknown, package unavailable). The owner reported to the clinic that vial of the product had an unpleasant smell. It is unknown if any of the other vials had the same smell. Product return not expected because vial was not available. No further information.

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Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
23-Oct-2019	UAE; 19US063971; OH; U.S.A	**Species:** Canine **Breed:** Beagle **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 28 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-Oct-2019	11-Oct-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Oct 2019, the owner reported the following event for a 28 pounds, Beagle (all other signalments unknown). Aug 2019: The dog was using a flea collar. 10 Oct 2019: The first vial of FRONTLINE PLUS DOG 23-44 LBS (S61727AL) was applied between the shoulder blades, by the pet owner. 11 Oct 2019: The dog had moderate amount of fleas for the first time. The dog does not get bathed. The owner is not seeing any flea activity in the household. The owner was the dog bedding and vacuum the home. The dog has access to an unknown area for bathroom breaks. There is 1 other dog in the household using FRONTLINE PLUS as well with case 19US062904. No further medical information is expected.
28-Oct-2019	UAE; 19US063991; KY; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2016*	01-Jan-2016*	0 Day(s)	D-A	Suspected Adverse Event: On 28 Oct 2019 the owner reported the following event for a canine of unknown signalment. Unknown Date: The pet received an unknown amount of FRONTLINE PLUS (lot unknown, package unavailable, product unsubstantiated) to an unknown location by an unknown route. The pet died from unknown circumstances after an unknown amount of time after the product was applied to the pet. It is unknown if the pet was presented to a veterinarian. The environment of the pet is unknown. It is unknown what condition the pet was in prior to the application. It is unknown if the pet had previous reactions to other medications. Case was previously reported, unable to locate case number, incident mentioned during report of a Suspected Lack of Efficacy , see case 19US063937. No further medical information expected.
29-Oct-2019	UAE; 19US064004; VA; U.S.A	**Species:** Feline **Breed:** Maine Coon Cat **Sex:** F **Sex qualifier:** Neutered **Age:** 15.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Jun-2019	01-Oct-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, the pet owner reported the following event for Prissy, a 15 year old, 8 pound, spayed female, Maine Coon. 14 Jun 2019: The cat began receiving FRONTLINE PLUS CATS (S40606AW) monthly. The product was applied directly on the skin between the shoulder blades. No fleas were seen prior to product application. 22 Sep 2019: The pet owner applied the product. 1 Oct 2019*: The owner is noticing the cat scratching and flea dirt. The cat has access to an open area outside, with trees and brush on the property. No treatments have been provided at home. 12 Oct 2019: The most recent date of application. The cat's current condition is ongoing. This is the only pet in the household. No further medical information expected.
29-Oct-2019	UAE; 19US064013; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 46 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Oatmeal Shampoo; **Route:** Topical / Cutaneous	01-Oct-2019	15-Oct-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, the pet owner reported the following event for 46 pound female canine of unknown signalment. History: The pet has received FRONTLINE PLUS DOG monthly for a few years. 1 Oct 2019: The owner applied FRONTLINE PLUS 45-88 LBS (S6316AX), 1 vial topically between the shoulder blades monthly. 15 Oct 2019*: The owner noticed small amount of fleas on the pet during a wellness visit to the veterinarian. The veterinarian applied a new unknown flea and tick product. The owner did not see any more fleas by the end of the day.

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* indicates Approximate date or weight.

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ED_005739D_00014391-00418

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					The owner has not noticed fleas off the pet inside the home. The pet is bathed once a month with oatmeal dog shampoo and does not have any skin issues. The yard is large and grassy. The pet is indoor/outdoor. There is a total of 1 canine and 2 felines in the household. The other pets are treated with FRONTLINE PLUS CAT and fleas are not seen on these pets. No further medical information expected.
29-Oct-2019	UAE; 19US064014; WI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 56 - 60 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Oct-2019	16-Oct-2019*	1 Day(s)	D-C	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 29 Oct 2019, the pet owner reported the following event for Korki, a 56.0 to 60.0 pound*, male canine, of further unknown signalment. 15 Oct 2019: The pet owner applied 1 dose of FRONTLINE PLUS (S61202AX), in one spot between the shoulder blades to the dog. 16 Oct 2019*: The pet owner found an engorged tick on the dog that was attached. She removed it. Unknown Dates: The pet owner has found 3 more ticks. One was a live tick and she has found areas on the skin, where it looks as if the ticks had been attached. Unknown Date: The pet owner noted that the dog is acting like he is in pain. The dog wakes up during the night and squeals and yelps. He has been treated with aspirin. The dog is in general good health and has access to woods, and the lawn with grass. The pet owner suspects the ticks are Deer ticks. The dog has received FRONTLINE PLUS DOG previously for approximately 10 years, monthly, year round and has not experienced any issues. No ticks have been seen in the home. No further medical information at this time.
29-Oct-2019	UAE; 19US064031; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 11.00 Week(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	11-Oct-2019	29-Oct-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, an owner reported the following event in an 11 week old, male canine of unknown further signalment. 11 Oct 2019: The owner administered one FRONTLINE PLUS DOGS 5-22 LBS (S61902AL) topically in-between the shoulders for the first time. No fleas or ticks were seen at the time of application. 29 Oct 2019: While bathing the dog the owner found one tick attched. The tick was removed, was still alive and engorged. The dog is indoor-outdoor in an unknown environment. There is one cat in the home. No further medical information expected.
29-Oct-2019	UAE; 19US064034; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** 1.50 Year(s) **Weight:** 45 - 80 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Oct-2019	10-Oct-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, the pet owner reported the following event for 3 canines, weighing between 45 and 80 pounds, ages ranging from 1.5 year to 6 years, mixed sexes and unknown breeds. History: The pets have received FRONTLINE PLUS 45-88 LBS (Lot unknown) (package unavailable) monthly year round for a few years. 5 Oct 2019: The owner bought a 6 pack and applied FRONTLINE PLUS 45-88 LBS (S61810AX), 1 vial per animal topically between the shoulder blades for the monthly dose. 10 Oct 2019*: The owner noticed an increase in scratching for all the pets and noticed a small amount of fleas on each. The owner has not noticed fleas off the pet inside the home. It is unknown if the pets are bathed and unknown if they have any skin issues. The environment is unknown. The pets have not presented

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ED_005739D_00014391-00419

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											to the veterinarian. The pets are indoor/outdoor. There are a total of 4 canines in the household. The other pet is treated with FRONTLINE PLUS 5-22 LBS and fleas are seen. See case 19US064047. No further medical information expected.
29-Oct-2019	UAE; 19US064037; PA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	13-Oct-2019	26-Oct-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, animal owner reported the following event for a female, Domestic shorthair cat. All other signalment is unknown. 13 Oct 2019: The cat presented as a stray to the pet owners farm. The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (Lot unknown/ package unavailable) topically between the shoulder blades for the first time. 26 Oct 2019: The pet owner removed an engorged tick from between the shoulder blades. The tick was alive and species is unknown. 27 Oct 2019: The pet owner found a tick that was attached and alive. The tick was removed. 28 Oct 2019: The pet owner found 3 ticks walking on the cats head. 29 Oct 2019: The pet owner removed one tick that was attached and alive. The cat is an indoor/ outdoor cat. The pet owner lives on a farm. There are other pets in the home on a non- BI preventative and the pet owner has not seen any ticks on those animals. No further information expected.
29-Oct-2019	UAE; 19US064044; IL; U.S.A	**Species:** Canine **Breed:** St. Bernard **Sex:** M **Sex qualifier:** - **Age:** 9.00 Year(s) **Weight:** 78 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Apr-2019*	07-Sep-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, the pet owner reported the following event for Charlie, a 9 year old, 78 pound intact male, Saint Bernard. 1 Apr 2011*: The dog began receiving FRONTLINE PLUS DOG 45-88 LBS (S61810AX) monthly from April to November. The product was applied directly on the skin between the shoulder blades. No fleas were seen prior to product application. 1 Sep 2019*: The pet owner applied the product. 7 Sep 2019*: The owner is noticing an unknown number of fleas and the dog scratching. The dog has access to an open area, with trees and brush on the property. The dog also goes for leash walks. 22 Oct 2019: The pet owner bathed the dog with Dawn dish soap. 27 Oct 2019: the most recent date of application. The dog's current condition is ongoing. There is also a cat in the household being treated with a non-company product, with no report of fleas. No further medical information expected.
29-Oct-2019	UAE; 19US064047; -; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** U **Sex qualifier:** Unknown **Age:** 1.50 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Oct-2018*	10-Oct-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, the pet owner reported the following event for a 1.5 year old 10 pound Shih Tzu of unknown further signalment. History: The pet has received FRONTLINE PLUS 5-22 LBS (Lot unknown) (package unavailable) monthly year round for a year. 5 Oct 2019: The owner bought a 6 pack and applied FRONTLINE PLUS 5-22 LBS (Lot unknown) (package unavailable), 1 vial topically between the shoulder blades for the monthly dose. 10 Oct 2019*: The owner noticed the pet scratching and noticed a small amount of fleas. The owner has not noticed fleas off the pet inside the home . It is unknown if the pet is bathed and unknown if the pet has any skin issues. The environment is unknown. The pet has not presented to the veterinarian. The pets are indoor/outdoor. There is a total of 4

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ED_005739D_00014391-00420

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											canines in the household. The other pets are treated with FRONTLINE PLUS 44-88 LBS and fleas are seen. See cases 19US064034. No further medical information expected.
29-Oct-2019	UAE; 19US064054; -; U.S.A	**Species:** Canine **Breed:** Havanese **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 14 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Oct-2019	29-Oct-2019*	4 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, the pet owner reported the following event for Behr, 14 pounds, 3 year, neutered male, Havanese. 01 Oct 2019: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 5-22 LBS (lot unknown/ package unavailable) to the skin between the shoulder blades for the first time after noticing the dog excessively scratching himself. 15 Oct 2019: The dog received a bath with an unknown canine shampoo. The owner applied a dose. 29 Oct 2019: The owner reports the pet is still scratching himself the same amount. There is 1 other dog and 1 cat in the home also on FRONTLINE PLUS not affected. The dog is outside for brief periods. There are no known prior skin conditions. There have been no fleas seen on the dog or in the home. No know outdoor cats or urban wildlife. No further medical information expected.
29-Oct-2019	UAE; 19US064058; -; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 7 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Dec-2017*	29-Oct-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, a pet owner reported the following event for Gizmo, a 2 year old, 7 pound, male neutered Maltese. Dec 2017*: The owner started Gizmo on FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable) topically between the shoulder blades and applies on a monthly basis year round. 18 Oct 2019: The most recent dose was applied. 29 Oct 2019: The owner is seeing several fleas. The owner does not bathe the dog, he does go the groomer. No other pets in the house. No further medical information expected.
22-Oct-2019	UAE; 19US064083; NY; U.S.A	**Species:** Feline **Breed:** Maine Coon Cat **Sex:** F **Sex qualifier:** Neutered **Age:** 18.00 Year(s) **Weight:** 7 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	08-Oct-2018*	08-Oct-2018*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Oct 2019, the pet owner reported the following event for Maddie, a 18 year old, 7 pound, spayed female, Maine Coon Cat. 8 Oct 2018*: The patient got their dose of FRONTLINE PLUS CAT (M40906AW). The animal has gotten a dose once every month since May 2019*. The owner purchased an unknown sized pack this past purchase, and the animal has used FRONTLINE whole life during the summer seasons ending in winter. It was applied between the shoulder blades. 9 Oct 2018*: The owner noticed ticks on the cat. The ticks were not identified, the owner removed them. The pet goes outside. The pet is showing no skin issues. The owner does not bathe the pet. The owner is not sure if they are in the house, she has not seen them. Howver she did see one on herself. The patient's current condition is recovered Maddie is the only feline in the household. No further medical information expected. UPDATE 04 Nov 2019: The cat also had a lack of efficacy report for 2019, see case 19US062649.
29-Oct-2019	UAE; 19US064090; MA; U.S.A	**Species:** Feline **Breed:** Feline (unknown)	1	1	0	**Product used:** FIPRONIL 10%/S	23-Oct-2019	29-Oct-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim and Adverse Event: On 29 Oct 2019, the pet owner reported the following event for Buddy, a 10 year old, 15 pound, neutered male, unknown breed feline.

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ED_005739D_00014391-00421

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 15 lbs				METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					23 Oct 2019: The cat received FRONTLINE PLUS CATS (S41305AW). The product was applied directly on the skin between the shoulder blades. This was the first time the owner has used the product. Fleas were seen prior to product application, and were biting humans in home. 29 Oct 2019: The owner is noticing the pet scratching. The cat is indoor only. No treatments have been provided at home. The cat's current condition is ongoing. This is the only pet in the household. No further medical information expected. UPDATE 18 Nov 2019: Per the owner, The pet is still scratching and fleas are still being seen on the pet. The pet was scratching prior to the application of FRONTLINE PLUS and is continuing to scratch. The pet is losing hair and has raw spots on his body from scratching. The pet has not been presented to a veterinarian for this issue. No further medical information expected.
29-Oct-2019	UAE; 19US064110; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	15-Oct-2019*	29-Oct-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, the pet owner reported the following event a canine of unknown signalment History: Owner had a previous flea infestation that cleared. Oct 2019*: The owner noticed an unknown amount of fleas on the pet. Oct 2019*: The owner applied FRONTLINE PLUS 23-44 LBS (Lot unknown) (reporter not quiered), an unknown dose by an unknown method. Owner is seeing a decrease in the number of fleas. The owner has not been noticing fleas off the pet inside the home. It is unknown if the pet is bathed or has any skin issues. The environment is unknown. It is unknown the pet has presented to the veterinarian. It is unknown the pet is indoor/outdoor. It is unknown if this is the only pet in the home. No further medical information expected.
29-Oct-2019	UAE; 19US064117; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Oct-2019*	29-Oct-2019*	4 Week(s)	D-A	Suspected Adverse Event: On 29 Oct 2019, an email was received at Boehringer Ingelheim and an owner reported the following event for a feline of unknown signalment. Unknown Date: The cat received FRONTLINE PLUS CATS (lot unknown, package unavailable) and expired an unknown amount of time after.
29-Oct-2019	UAE; 19US064122; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** - **Weight:** 50 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	29-Oct-2019	29-Oct-2019	0 Day(s)	D-D	Suspected Adverse Event: On the 29 Oct 2019, a pet owner reported the following event for a 50 pound, spayed female, canine of unknown further signalment. 29 Oct 2019: The pet owner applied for the first time 1 dose of FRONTLINE PLUS DOG 45-88 LBS (unknown lot number, package unavailable) topically between the shoulder blades. About 10 minutes later the dog developed a hacking, gagging sound. The pet owner is unsure if she is having difficulty breathing. The pet owner has not presented the dog to the veterinarian and she has not received any treatment. The issued is ongoing. No further medical information expected.

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ED_005739D_00014391-00422

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					
29-Oct-2019	UAE; 19US064128; OR; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** M **Sex qualifier:** Neutered **Age:** 17.00 Year(s) **Weight:** 85 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Oct-2019*	29-Oct-2019*	26 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019 a pet owner called to report the following event in Jake, a 17 year old, 85.0 pound, neutered male, Black Labrador Retriever canine. 3 Sep 2019*: The pet owner observed the dog itching and suspects she found flea dirt on the dog while brushing him. The pet owner has not observed any live fleas. 3 Oct 2019*: The pet owner applied FRONTLINE PLUS (P61601) in between the shoulder blades of the dog for the first time this year. 29 Oct 2019: The dog is still itching. The pet owner still has not seen any fleas, but has seen something that looks like flea dirt. The pet owner is visually challenged and is not sure if she has seen flea dirt or not. The dog has access to a back yard. There are no other animals in the home. No further medical information expected. UPDATE 27 Nov 2019: Per the pet owner, 3 Nov 2019: The owner continued to notice an unknown amount of fleas on the pet. The pet was scratching and chewing, and flea dirt was noted on the pet. The owner applied FRONTLINE PLUS to the pet. 15 Nov 2019*: The owner continues to notice an unknown amount of fleas on the pet. The owner noticed one live flea on the pets bedding. There are no fleas seen in the home. The pet has continued to chew and scratch. No further medical information expected.
29-Oct-2019	UAE; 19US064142; CA; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 60 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Mar-2019*	02-May-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, the pet owner reported the following event for Deck, a 5 year old, 60 pound, neutered male, Pitbull. Mar 2019*: The dog began receiving FRONTLINE PLUS 45-88 LBS (S62408AX) monthly. The product was applied directly on the skin between the shoulder blades. No fleas were seen prior to product application. 1 May 2019*: The owner applied the product. 2 May 2019*: The owner noticed an unknown number of fleas. The dog is outdoor only, and lives in a fenced in yard with trees and brush on the property. 1 Jun 2019* - 1 Sep 2019*: The pet owner applied the product monthly. 1 Oct 2019*: The most recent date of application. 29 Oct 2019: The pet owner is continuing to see fleas. No treatments have been provided at home. The dog's current condition is ongoing. This is the only pet in the household. No further medical information expected.
29-Oct-2019	UAE; 19US064147; OH; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** Neutered **Age:** 2.50 Year(s) **Weight:** 16.5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	14-Aug-2019	05-Sep-2019*	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 Oct 2019, the pet owner reported the following event for Skittles, 16.5 pounds, 2.5 years, neutered male, Chihuahua mix. 14 Aug 2017*: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 5-22 LBS (S61902AL) to the skin between the shoulder blades monthly for the first time. 14 Aug 2019: The owner applied a dose. 05 Sep 2019*: The owner began to see 4 to 5 live fleas on the dog daily. 14 Sep 2019: A dose was applied. 28 Sep 2019*: The dog was bathed with Dawn dish soap every

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ED_005739D_00014391-00423