Date case Received	Case type; Case Reference; 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 exposed to a grass yard and there is one other dog treated dog in the home who also is having a tick issue. See case 19US029747. No further information available.
29-May-2019	UAE; 19US029788; -; U.S.A	**Species:** Canine **Breed:** Beagle **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 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	01-May-2019	28-May-2019	27 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 May 2019, the pet owner reported the following event for Rosie, a 7 month old, 16 pound, spayed female Beagle. 1 Apr 2019: The dog began receiving monthly doses of FRONTLINE PLUS DOG 5-22 LBS (S60302AL) with the most recent application on 1 May 2019. 28 May 2019: The owner removed 5 ticks which were attached to the dog; 4 ticks from the inside of the ear and 1 tick from the dog's side. No further medical information expected.
29-May-2019	UAE; 19US029791; MO; U.S.A	**Species:** Canine **Breed:** Catahoula **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 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	29-Apr-2019	28-May-2019	29 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 May 2019, the owner reported the following event for Myx, 2 year old, 65 pound, spayed female, Catahoula canine. 29 Apr 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S61313AR) was applied between the shoulder blades. 28 May 2019: The owner removed 50 attached ticks. The majority of the ticks were still alive. The dog has access to a heavily wooded area. The dog has received the product seasonally since 2017* with no issue. There are no other pets in the household. No further medical information is expected.
29-May-2019	UAE; 19US029820; -; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 4 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	19-May-2019*	28-May-2019*	9 Day(s)	D-C	Suspected Adverse Event: On 29 May 2019, the pet owner reported the following event for a 4 pound*, female, small crossbred canine of further unknown signalment. 19 May 2019*: The canine received unknown FRONTLINE (lot unknown) (product unsubstantiated) via unknown route. It's unknown if she's previously received this product. 28 May 2019*: She began hypersalivating. She was hospitalized for the day at the veterinary clinic, but it can't be confirmed what diagnostics and/or treatment was performed, if any at all. 29 May 2019*: The canine began experiencing emesis, hemmorhagic diarrhea, and undefined seizures. The pet owner declined to provide additional details. No further medical information expected.
30-May-2019	UAE; 19US029869; -; 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:** Advantage; Revolution; **Route:** unknown **Was the product used**	27-May-2019	29-May-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 May 2019, a pet owner reported the following event for a feline of unknown signalment. 27 May 2019: The owner applied FRONTLINE PLUS CATS (lot unknown). 29 May 2019: The owner is seeing ticks. The owner is switching between Advantage and Revolution on unknown dates. All further details are unknown. No further medical information 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
						ok?: Unknown to Company					
25-May-2019	UAE; 19US029876; GA; 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	25-May-2019	25-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 May 2019 an animal owner reported via email the following event in a cat. 25 Dec 18*: Feline started receiving monthly doses of FRONTLINE PLUS CATS (lot, expiration unknown). 25 May 2019: The animal owner reports no results seen. Multiple attempts with no response. No further information expected.
29-May-2019	UAE; 19US029888; KY; U.S.A	**Species:** Canine **Breed:** Boston Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 13.00 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	01-Apr-2019	07-Apr-2019	6 Day(s)	D-D	Suspected Adverse Event: On 29 May 2019, the owner reported the following event for Zeus, 13 year old, 25 pound, neutered male, Boston Terrier canine. 1 Apr 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (G64612AL) was applied between the shoulder blades. 7 Apr 2019: The dog experienced dry skin. The pet did not present to the clinic. The owner treated by bathing once a week. Unknown date: The dog recovered. The dog has received the product since 2018* and the same symptoms occur after each dose. No further medical information is expected.
29-May-2019	UAE; 19US029894; -; 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	29-May-2019*	29-May-2019	immediately after application	D-D	Suspected Adverse Event: On the 29 May 2019, a pet owner reported the following event for a female feline of unknown further signalment. 29 May 2019: The pet owner applied topically 1 dose of FRONTLINE PLUS CATS (unknown lot number) between the shoulder blades. Immediately after the cats eyes became glassy. The owner suspects she ingested some of the product after she applied it to the cat. The symptom is ongoing. The cat does not have any other symptoms and the owner stated the cat is fine she just saw that the eyes got glassy. It is unknown if the owner has applied the product in the past. No additional information is expected as the owner refused to give additional details as she feels this is not a reaction. No further medical information expected.
29-May-2019	UAE; 19US029901; NJ; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 65 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Interceptor; **Route:** Topical / Cutaneous **Was the**	13-May-2019	25-May-2019	12 Day(s)	D-C	Suspected Adverse Event: On 29 May 2019, the pet owner reported the following event for Piper a female spayed, 65 pound, 7 year old, Retriever Labrador/Siberian Husky crossbreed. 13 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (S61306AR) topically to skin between the shoulder blades of Piper. Piper was administered unknown amount Interceptor for heartworm. 25 May 2019: The pet owner noticed chemical burn at application site of Piper. 28 May 2019: Piper was presented to veterinarian and treated with Cefpodoxime. 29 May 2019: Piper was in good health at time of application. Piper

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						product used ok?: Yes					does not have history of drug or vaccine reactions. Piper has had FRONTLINE prior to reaction on year round basis every month. Piper is currently at home with ongoing issue. No further medical information.
28-May-2019	UAE; 19US029910; NJ; U.S.A	**Species:** Canine **Breed:** American Bully **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 120 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-May-2019	21-May-2019	0 Day(s)	D-D	Suspected Adverse Event: On 29 May 2019, the owner reported the following event for the Murphy, a 120 pound, 7 year old, male, neutered, American Bully. 21 May 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (Lot Unknown) was applied topically in one location in-between the shoulder blades by the pet owner. Within 24 hours the owner noticed skin irritation at the application site and around the pets body with pus filled bumps and reactive to touch on the skin. 24 may 2019: The pet was presented to the clinic and given Benedryl tablet, a Steroid injection and an unknown anti-biotic. 28 May 2019: The pet's symptoms are ongoing. The pet has used FRONTLINE PLUS DOG 89-132 LBS in the past with no reactions on a year round basis since May 2017. There is another pet in the home that had a similar reaction see case 19US029572. No further medical information expected at this time.
29-May-2019	UAE; 19US029958; -; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 7 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Advantage; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Apr-2019*	30-Apr-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 May 2019, the pet owner reported the following event for Benji, a 6 year old*, 7 pound, neutered male, Yorkshire Terrier. Unknown dates: Spanning an unknown duration, the canine received one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) applied topically in between the shoulder blades. An unknown time afterwards, he received unknown doses of Advantage. 28 Apr 2019*: Benji received one vial of FRONTLINE PLUS DOG 5-22 LBS applied as described above. The dose was administered proactively. Unknown dates: An unknown duration following product application, the reporter observed an unknown quantity of ticks spanning an unknown length of time. He's unable to recall the condition of the ticks including whether they were live, deceased, attached, engorged, and/or the species. On an unknown recent date, he observed four ticks and every time upon finding said ticks, each was manually removed. 28 May 2019: Another vial of FRONTLINE PLUS DOG 5-22 LBS was applied as previously described. Presently, no further action and/or treatment has been taken. There are no other dogs in the home and the event is ongoing. No further medical information expected.
28-May-2019	UAE; 19US029974; VA; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 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	26-Apr-2019*	28-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 28 May 2019, a pet owner reported the following event for Prissy, a 9 year old (born 1 Apr 2010), 16 pound, Shih Tzu. 26 Apr 2019*: The dog received 1 application of FRONTLINE PLUS DOG 5-22 LBS (R62514AL), topically for the first time. An unknown amount of time later, the dog started scratching. It is unknown if the scratching was continuous or resolved. 26 May 2019: The dog received the most recent application. An unknown amount of time later, the dog was scratching. It is unknown if the scratching was continuous or resolved. 28 May 2019: The pet owner noticed that the dog was scratching and saw a live flea on the dog. The dog has access to a fenced in yard with grass, no crawl

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											spaces or decks. The dog goes to the groomer every 4-5 weeks, and does not have a history of skin issues. The owner is unsure if fleas were noticed prior to starting on FRONTLINE. There is 1 other dog in the house that shares product and also has a case, see 19US029687. No further medical information expected. UPDATE 15 Jul 2019: Per the owner, most recent application of FRONTLINE was on 28 Jun 2019. 12 Jul 2019: The owner was still seeing fleas. No further medical information expected.
29-May-2019	UAE; 19US029976; FL; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 60 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	26-May-2019	29-May-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 May 2019, the owner reported the following event for (2) 60 pound large mixed breed dogs. 26 May 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (R62001AR) was topically applied to the skin between the shoulder blades for the first time. 29 May 2019: The owner found 4 attached large white ticks on the dogs that were removed. The environment is unknown and it is unknown if there are any other pets in the home. No further information available.
29-May-2019	UAE; 19US029990; FL; U.S.A	**Species:** Feline **Breed:** Maine Coon Cat **Sex:** F **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 product used ok?:** Yes	18-May-2019	19-May-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 May 2019, a pet owner reported the following event for Ruby, a 9 year old, 12 pound, spayed female Maine Coon Cat. 18 Apr 2019: The cat received 1 application of FRONTLINE PLUS CATS (S40606AW) topically at the base of the neck between the shoulders blades for the first time. 18 May 2019: The most recent application was applied. 19 May 2019*: The cat began scratching all over. The owner states that the scratching has continued daily. 27 May 2019: The owner found 2 live fleas on the cat's abdomen. There are no other pets in the house. The cat does have access to a fenced in yard and underneath a shed. The cat does not get baths and does not have a history of skin issues. The cat does like to hunt. The owner has not noticed any ticks on the cat and has not seen any flea activity in the house. No further medical information expected.
29-May-2019	UAE; 19US029997; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	9	9	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-Jan-2019*	01-May-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 May 2019, the owner reported the following event for 9 unknown canines, weighing various sizes, other signalment unknown. 1 May 2019: One vial of the FRONTLINE PLUS DOG 89-132 LBS (P61204AR) was applied by a dropper per the pet's weight by the owner. May 2019*: The owner noticed 8-9 fleas on all of the pets for about a month. The pets are fosters and are indoor mostly and go outside for potty breaks and recreation. The owner treats on a year round basis depending on who is in her care at the time. This is the owner's first time seeing fleas with the use of the product. Owner purchases a 3 pack every month and applies on the first. FRONTLINE. The owner is also using a Natural Citronella Flea Spray at an unknown frequency. No further medical information is expected

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30-May-2019	UAE; 19US030111; IL; U.S.A	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 22 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Predinisone; Doxycyline; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-May-2019	05-May-2019	0 Day(s)	D-C	Suspected Adverse Event: On 30 May 2019, the pet owner reported the following event for Bella, a 7 year old, 22 pound, female spayed, Poodle (Miniature). 5 May 2019: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S60714AX) was applied to the dog in one area between the shoulder blades. Later in the day the dog could not lift her legs and was unable to walk for 3-4 days. She had pain in her front right paw and trouble getting up and down. 8 May 2019*: She recovered and was able to walk. She was diagnosed with Lyme disease 4 weeks ago (2 May 2019*). The dog was treated with Doxycycline and Prednisone. She was not 100% before application of FRONTLINE, she was having trouble with her legs from Lyme disease diagnosis. She was not seen by the Veterinarian, no treatments were provided. There is one other dog in the home that received FRONTLINE PLUS and experienced symptoms, see case 19US31445. The dog has been on FRONTLINE PLUS monthly since 2012. No further medical information is expected. UPDATE 25JUN19: After further review, change made to route in product screen data entry. No further medical information is expected.
29-May-2019	UAE; 19US030114; NC; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 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	27-May-2019	27-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 29 May 2019, the pet owner reported the following event for Lady Desire, a 90 pound, 12 year old, female spayed, Australian Shepherd. 27 Mar 2019: The dog was not having an issue with fleas. 1 vial of FRONTLINE PLUS DOG 89-132 LBS (M62802AR) was applied to the dog in one area between the shoulder blades for the first time of the season. The owner was seeing large amount of fleas on the dog every day since the application. 27 Apr 2019: 1 vial of FRONTLINE was applied to the dog. The owner was seeing large amount of fleas on the dog everyday since the application. 27 May 2019: 1 vial of FRONTLINE was applied to the dog. The owner has been seeing large amount of fleas on the dog everyday since the application. The fleas are migrating to the dogs face. There are fleas present in the home biting the humans. The dog goes out for potty breaks and recreation in fenced in yard. The dog has no history of skin issues. The dog was bathed prior to the application of FRONTLINE with an oatmeal shampoo at an unknown date. No further medical information is expected.
29-May-2019	UAE; 19US030116; CA; U.S.A	**Species:** Feline **Breed:** American Shorthair **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 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 / Cutaneous **Was the product used ok?:** Yes	28-May-2018*	29-May-2019	1 Day(s)	D-D	Suspected Adverse Event: On 29 May 2019, the owner reported the following event for Simba, a 3 year old, 11 pound, neutered male American Shorthair. 28 May 2019: One vial of FRONTLINE PLUS CATS (S40606AW) was topically applied to the skin between the shoulder blades. 29 May 2019: Simba vomited once and recovered without vet assistance. Simba has had FL for at least a year without issues. There are two other treated cats in the home, one cat was fine after the application and the other cat also vomited, see case 19US030321. No further information available.
30-May-2019	UAE; 19US030166; OH; U.S.A	**Species:** Canine **Breed:** Pinscher (Miniature)	1	1	0	**Product used:** FIPRONIL 10%/S	01-Mar-2019*	02-Mar-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019, the owner reported the following event for Mig, 3 year old, 13 pound, intact spayed, Miniature Pinscher canine.

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		Sex: F **Sex qualifier:** - **Age:** 3.00 Year(s) **Weight:** 13 lbs				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					1 Mar 2019*: The owner started to notice fleas, and the pet itching. The owner purchased a 6 pack of FRONTLINE PLUS DOG 5-22 LBS (lot unknown). One vial was applied between the shoulder blades. 2 Mar 2019*: The flea issue and itching persisted. 1 Apr 2019*, 30 Apr 2019*: Another vial was applied. The owner continued to find fleas sporadically. 30 May 2019: The issue is still ongoing. The owner bathed the pet monthly with an unknown flea shampoo. The dog has access to a small portion of the yard. There are no other pets in the household. The dog has received the product on a year round basis since 2017* with no issue. No further medical information is expected.
30-May-2019	UAE; 19US030215; -; U.S.A	**Species:** Canine **Breed:** Hound Breeds (200 Series) **Sex:** F **Sex qualifier:** Neutered **Age:** 13.50 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-May-2019	21-May-2019*	1 Day(s)	D-C	Suspected Adverse Event: On 30 May 2019, the pet owner reported the following event for Molly, a 40 pound, 13.5 year old*, spayed female Hound mix. 20 May 2019: Molly was given 1 dose of FRONTLINE PLUS DOG 23-44 LBS (S61009AL) topically in the neck region. 21 May 2019*: Molly became anorexic and could not stand. The owner washed her neck area with dish soap. About 3-4 hours later, Molly recovered. Molly has been receiving the pproduct since Jan 2018* withiut any adverse event. She does not have a history of drug or vaccine reaction. no further information at this time.
30-May-2019	UAE; 19US030227; SC; 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:** unknown **Was the product used ok?:** Unknown to Company	30-May-2019*	30-May-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019, the pet owner reported the following event for canine, 40 pounds, other signalment unknown. 30 May 2019*: The pet owner reported that his dog was infested with fleas after application of FRONTLINE PLUS 23-44 LBS (lot number unknown). No further medical information.
30-May-2019	UAE; 19US030252; NC; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.50 Year(s) **Weight:** 12 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	25-May-2019	25-May-2019	0 Day(s)	D-D	Suspected Adverse Event: On 30 May 2019, the pet owner reported the following event for Cali a female spayed, 12 pound, 2.5 year old, other signalment unknown. 25 May 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (P41102AX) topically to skin between the shoulder blades of Cali for the first time. After approximately 1.5 hours* post application the pet owner noticed Cali experience lethargy and had vomited twice. 30 May 2019: Cali was in good health at time of application. Cali was not presented to veterinarian. Cali has not had any other products at the same time as the FRONTLINE PLUS CATS application. Cali does not have history of drug or vaccine reactions. Cali has not had FRONTLINE prior to reaction. Cali is strictly indoors. Cali is currently at home with ongoing issue of lethargy but recovered from vomiting. Cali shares FRONTLINE PLUS CATS with one other cat in the home with no issues. No further medical information

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30-May-2019	UAE; 19US030278; TX; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** X **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 6.5 - 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	18-May-2019	19-May-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019, the pet owner reported the following event for Desmond a male neutered, 11 pound, 8 year old, feline mixed/various breeds. The pet owner also reported the following event for Dahlila, a female spayed, 6.5 pound, 2 year old, feline mixed/various breeds. The pet owner also reported the following event for Leo, a male neutered, 3 year old, 12 pound, feline mixed/various breeds. 30 Apr 2019*: The pet owner first noticed 1-5* fleas on the bodies of the cats. 18 May 2019: The pet owner applied one dose of FRONTLINE PLUS CATS topically to skin between the shoulder blades of the cats monthly on year round basis since May 2018 with 1-5 fleas. 19 May 2019: The pet owner continued to see 1-5 fleas on the cats. 30 May 2019: The cats were in good health at time of application. The cats were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. The cats have no history of skin problems or any other issues with topical treatments. The cats have not had flea problem before in the past. The cats have not received any other medications or topical treatments. The cats have not been bathed. The cats are strictly indoors. The current status of the cats are unknown. No further medical information.
30-May-2019	UAE; 19US030286; -; 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?:** No (zzOff label use / Indication)	15-May-2019	30-May-2019	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019 a pet owner reported the following event for a canine of unknown signalment. 1 May 2019: The owner applied 1 dose of FRONTLINE PLUS DOG 5-22 LBS (LOT UNKNOWN) between the shoulders, the dog had fleas prior to application. 15 May 2019: The owner applied another dose of FRONTLINE PLUS between the shoulders. 30 May 2019: The dog still has fleas and is scratching. There is another dog in the house that is having the same issue, see case 19US030285. Owner refused to provide further details. No further medical information expected.
30-May-2019	UAE; 19US030294; TX; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 6 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	16-May-2019*	30-May-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019 an animal owner reported the following event in her 3 dogs that weigh approximately 6 pounds. All other signalment was not reported. 16 May 2019*: The canines were administered 1 entire vial each of FRONTLINE PLUS 5-22 pounds (lot, expiration unknown). No fleas were seen at time of administration. 25 May 2019: The canines were bathed with a human shampoo. 30 May 2019: The animal owner saw an unreported number of fleas on all 3 dogs' faces. Animal owner unwilling to give further case details. No further information provided nor expected.
30-May-2019	UAE; 19US030296; TX; U.S.A	**Species:** Canine **Breed:** Boxer **Sex:** F **Sex qualifier:** -	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	20-May-2019*	21-May-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019, the pet owner reported the following event for Pixie a female intact, non-pregnant non-lactating, 56 pound, 10 year old, Boxer. 20 May 2019*: The pet owner first noticed 15+ fleas on the body of

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		Age: 10.00 Year(s) **Weight:** 56 lbs				9% SPOT ON **Other products used:** Dawn dish soap; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)					Pixie. The pet owner bathed Pixie with Dawn dish soap. The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (lot number unknown) topically to skin between the shoulder blades of Pixie on year round basis every month since May 2018 with 15+ fleas. 21 May 2019: The pet owner continued to see 15+ fleas on the body of Pixie. 30 May 2019: Pixie was in good health at time of application. Pixie was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has seen fleas in the home. Pixie has no history of skin problems or any other issues with topical treatments. Pixie has not had flea problem before in the past. Pixie has not received any other medications or topical treatments. Pixie is indoors and outside in fenced yard. The current status of Pixie is unknown. Pixie shares FRONTLINE PLUS DOG 45-88 LBS with 2 other dogs that have flea issues. Pixie also shares home with additional 3 dogs that have flea issues treated with FRONTLINE PLUS DOG 5-22 LBS (lot number unknown). No further medical information.
30-May-2019	UAE; 19US030302; PA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 9 lbs	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-May-2019*	04-May-2019*	3 Day(s)	D-A	Suspected Adverse Event: On 30 May 2019, the clinic reported the following event for Mance, 3 years old, 9 pounds, neutered male, Domestic Shorthair (crossbreed). 1 May 2019*: One vial of FRONTLINE PLUS CATS (540606) (Invalid lot) was applied between the shoulder blades, by the pet owner. 4 May 2019*: The cat had seizure like activity and was walking into walls disoriented. 13 May 2019: The cat presented to clinic. The veterinarian did a comprehensive exam, bloodwork and administered and unknown amount of fluids. Antibiotics were prescribed to the cat. 17 May 2019:The cat presented to clinic again because the pet owner stated it was declining in health. The veterinarian did a pre-anesthetic blood panel and gave an unknown amount of fluids. The clinic stated that those results were showing improvement. 21 May 2019: The pet owner reported to the clinic that the pet was having multiple seizures at home. 23 May 2019: The presented to clinic for having a seizure earlier in the day. The clinic gave an injection of an unknown amount of diazepam. The veterinarian prescribed phenobarbital. 30 May 2019: The cat was euthanised at another clinic. No further medical information is expected. UPDATE 4 Jun 2019: As reported by the veterinarian, the cat was in good health at the time FRONTLINE PLUS was applied. The product was obtained from a feed store and the product package was not available. On 13 May 2019, blood work was performed and the cat had elevated renal values. The cat was treated with SC fluids and an unknown antibiotic. The cat improved for 3-4 days but then symptoms returned. The veterinarian's level of suspicion that FRONTLINE PLUS caused the clinical signs is high. No further information is expected.
30-May-2019	UAE; 19US030314; MN; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** F **Sex qualifier:** Neutered	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	26-May-2019	26-May-2019	7 Week(s) 6 Day(s)	D-A	Suspected Lack of Efficacy Claim: On the 30 May 2019, an office manager reported the following event for Lucy, a 51 pound, 2 year old (born 10 Aug 2016), spayed female, Black Labrador Retrirever. 11 Oct 2016: The dog started on monthly NEXGARD (68 mg) (lot and expiry unknown with 1 chew administered PO by the pet owner with the following purchase history: 1 chew on 11 Oct 2016, 1 chew on 25 Oct 2016, 2 chews on 15 Nov 2016, 1 chew on 24 Feb 2017,

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		Age: 2.00 Year(s) **Weight:** 51 lbs				**used:** RECOMBITEK LYME - 2126.R0; AFOXOLANER 68 MG CHEWABLE TABLETS; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					1 chew on 30 Mar 2017, 6 chews on 21 Jul 2017, 7 chews on 9 May 2018 and the vet sent a script to an online pharmacy on 29 Apr 2019. 15 Nov 2016: The dog was vaccinated for the first time with RECOMBITEK LYME (42226, 27 Mar 2020), 1 ml, SC, in the hip, left by the veterinarian with a booster given on the following dates: 24 Dec 2016, 9 Oct 2017 and 22 Sep 2018. 26 May 2019: The dog presented to the emergency clinic because she had ingested a corn cob and was not eating and drinking water. There they induced vomiting and was sent home. 28 May 2019: The dog was still anorexic and adipsic, she presented to the regular veterinarian who performed a physical exam and a CBC/Chemistry and UA with the following abnormalities: RBC: 4.16 (reference range: 4.48-8.53), Hemoglobin: 10.2 (refernce range: 10.5-20.1), hematocrit: 29.6 (reference range: 33.0-58.7) Lymphocytes: 3.96 (reference range: .3-3.9) Cholesterol: 302 (reference range: 98.-300, total protein: 4.9 (reference range: 5.0-8.3), Albumin: 1.2 (reference range: 2.6-4.0), Urea Nitrogen: 92 (reference range: 8-30), creatinine: 4.5 (reference range: .4-2.0), phosphorus: 9.6 (reference range: 2.5-7.9) ,calcium: 8.6 (reference range: 8.7-12.0), GGT: 1 (reference range: 3-19). The vet diagnosed as renal hepatic. The veterinarian then referred the dog to the emergency clinic. While at the emergency clinic the dog tested lyme nephritis positive via an unknown test. The dog is currently hospitalized at the emergency clinic with unknown treatment. The dog was never tested for lyme
30-May-2019	UAE; 19US030320; FL; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 10 - 13 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Vitamin D and Vitamin C; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-May-2019*	30-May-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019, the pet owner reported the following event for Gizmo, male neutered, 10 pound, 6 year old, Mixed Breed/various. The pet owner also reported the following event for Sailor, male neutered, 7 year old, Bichon Frise. 20 May 2019*: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S62106AL) topically to skin between the shoulder blades of the dogs monthly on year round basis since May 2018. 30 May 2019: The pet owner first noticed 15+ fleas on the body of the dogs . The dogs were in good health at time of application. The dogs were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. The dogs have no history of skin problems or any other issues with topical treatments. The dogs have not had flea problem before in the past. The dogs have not received topical treatments, but does take vitamin D and vitamin C on unknown dates. The dogs are indoors and outside for walks. The current status of the dogs are unknown. No further medical information.
29-May-2019	UAE; 19US030321; CA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 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**	28-May-2019	29-May-2019	1 Day(s)	D-D	Suspected Adverse Event: On 29 May 2019, the owner reported the following event for Pippa, a 7 year old, 14 pound, spayed female Domestic Longhair. 28 May 2019: One vial of FRONTLINE PLUS CATS (S40606AW) was topically applied the skin between the shoulder blades. 29 May 2019: Pippa vomited once and recovered without vet assistance. Pippa has had FL for at least a year without issues . There are two other treated cats in the home, one cat was fine after the application and the other cat also vomited. See case 19US 030116. No further information available.

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						product used ok?: Yes					
30-May-2019	UAE; 19US030378; NC; U.S.A	**Species:** Canine **Breed:** West Highland White **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	01-Jan-2005*	16-May-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019, the owner reported the following event for Andy, a 20 pound, male neutered, 15 year old, West Highland White Terrier. 30 Apr 2019: One vial of the FRONTLINE PLUS DOG 5-22 LBS (S61412AL) was applied topically in between the shoulder blades by the owner. 16 May 2019: The owner noticed a small amount of fleas and flea dirt on both pet. The pet is indoor mostly and goes outside for potty breaks. The pet has access to a fenced in yard were urban wildlife is seen on occasion. This is the first time the owner has seen fleas on the pet since using the product from when the pet was 8 weeks old in 2005*. The owner is bathing the pet in Pharmaseb Shampoo at an unknown frequency.No further medical information is expected
30-May-2019	UAE; 19US030396; TX; U.S.A	**Species:** Canine **Breed:** Great Pyrenees **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 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	21-May-2019	24-May-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019, Animal owner reported the following event for Nobu, a 2 year old, 80 pound, neutered male great pyrenees mix. Oct 2017: Started monthly FRONTLINE PLUS DOG 45-88 LBS (Lot unknown) topically between the shoulder blades. 21 May 2019: The pet owner applied the full contents of 1 vial topically to the back of the neck. 23 May 2019: The dog went to the dog park and went swimming. 24 May 2019: The pet owner started seeing fleas on the dog. The pet owner reported the fleas vary in size and are alive. There is a cat in the home who also received FRONTLINE PLUS FOR CATS and does not have fleas. The pet owner stated she has never seen fleas on her dog since she initially used the product and she uses the product every month all year round. She has not seen any fleas in her home and the environment has not been treated. No further information expected.
30-May-2019	UAE; 19US030421; -; 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	30-May-2019*	30-May-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 30 May 2019 an animal owner reported the following event in a canine. All other signalment unknown. 30 May 2019*: The canine was administered FRONTLINE PLUS 23-44 lb (lot, expiration unknown). Post administration and a walk, the canine became lethargic. Animal owner not willing to give further details. No further information provided nor expected.
30-May-2019	UAE; 19US030438; CA; U.S.A	**Species:** Feline **Breed:** Maine Coon Cat **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 /	16-May-2019	16-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019, the pet owner reported the following event for a Maine Coon Cat and an Exotic Shorthair, additional signalment unknown. 16 Feb 2019*: Pet owner began using FRONTLINE PLUS CATS (lot unknown) (FL) topically in an unknown manner. Prior to the application, the pet owner was finding fleas on the cats. Pet owner continued to apply to the cats monthly. 16 May 2019: Cats received most recent treatment of FL. Following the application, the pet owner stated that fleas are still on

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						Cutaneous **Was the product used ok?:** Unknown to Company					the cats, along with flea dirt. There is no reported flea activity in the home, only on the cats. The cats are primarily indoors, but they do go outside on occasion. No further medical information expected.
30-May-2019	UAE; 19US030440; NY; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Month(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	16-May-2019	21-May-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019, a pet owner reported the following event for Melanie, a 5 month old (born 26 Nov 2018), 9 pound, spayed female Chihuahua. 16 May 2019: The dog received 1 application of FRONTLINE PLUS DOG 0-22 LBS (S63009BL) topically between the shoulder blades for the first time. 21 May 2019*: The pet owner noticed 5 ticks of different sizes on the dog. All of them were attached and 1 was engorged. There is 1 cat in the house that does not go outside and is on FRONTLINE. The yard is fenced in and is surrounded by a nature preserve. The pet owner was concerned that the product's formula had changed because she had used FRONTLINE in the past on another dog and never had any issues with tick. No further medical information expected.
30-May-2019	UAE; 19US030451; SC; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **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:** Tropiclean flea and tick shampoo; IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	26-May-2018*	26-May-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019, the pet owner reported the following event for Sade a female spayed, 48 pound, 11 year old, Large crossbreed. Unknown dates: The pet owner administers unknown amount HEARTGARD PLUS (lot number, expiration unknown) (product unsubstantiated) for heartworm to Sade. 26 May 2019: The pet owner noticed 5-6* fleas on the body of Sade. The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (P61701) topically to skin between the shoulder blades of Sade monthly on year round basis. The pet owner bathed Sade with Tropiclean flea and tick shampoo. 27 May 2019: The pet owner continued to see 5-6* fleas on the body of Sade. 30 May 2019: Sade was in good health at time of application. Sade was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen any fleas in the home. Sade has no history of skin problems or any other issues with topical treatments. Sade has not had flea problem before in the past. Sade has not received any other topical treatments. Sade is indoors and outside in fenced yard. The current status of Sade is unknown. Sade share home with 1 other cats that are not treated FRONTLINE PLUS CATS with no flea issues. No further medical information. UPDATE 15 Jul 2019: Expected? was selected No for Heartgard Plus on the assessment screen.
22-May-2019	UAE; 19US030455; CA; U.S.A	**Species:** Feline **Breed:** Burmese **Sex:** F **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**	05-May-2019	19-May-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 22 May 2019, the owner reported the following event for a 10 pounds, female, Burmese (all other signalments unknown). 5 May 2019: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. This was the first time using the product. 19 May 2019*: The cat had a moderate amount of fleas. The cat does not get bathed. The owner is not seeing any flea activity in the home. The cat is strictly indoors. Please see case 19US028720 for another event regarding the same pet and FRONTLINE PLUS CATS. No further medical information is expected.

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						ok?: Yes					
28-May-2019	UAE; 19US030456; MS; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 18.00 Year(s) **Weight:** 9 lbs	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-Jan-2013*	01-Jan-2013*	0 Day(s)	D-A	Suspected Adverse Event: On 28 May 2019, the owner reported the following event for Molly, 18 year old, 9 pound, spayed female, Domestic Longhair feline. 2013*: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades on a seasonal basis. The cat experienced strange behavior like the product burned. There was no visible irritation on the pet. The pet did not present to the clinic and no treatment was provided. The cat recovered after an unknown period of time. The cat passed away on another unknown date. The pet has received the product since 2001* with the same symptoms. There is 1 other cats and a dog in the household that received the FRONTLINE and experienced symptoms (see case 19US029566, and 19US029456). No further medical information is expected.
31-May-2019	UAE; 19US030466; OH; 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	27-May-2019	30-May-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the owner reported the following event for an Unknown male feline, all other signalment unknown. 27 May 2019: One vial of FRONTLINE PLUS CATS (Lot Unknown) was applied topically in between the pets' shoulder blades by the owner. 30 May 2019: The owner noticed a small amount of fleas on the pet. The cat is strictly indoor. 2 fleas noticed in the home. This is the first dose for the pet. The owner noticed the fleas in the home before he noticed them on the pet. This is the first time fleas have been seen on the pet. The owner is treating the home. No further medical information expected.
31-May-2019	UAE; 19US030470; MI; U.S.A	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 7 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	30-Apr-2019	14-May-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019 a pet owner reported the following event for Mikkie, a 7 pound, female Miniature Poodle of unknown age and reproductive status. 30 Apr 2019: Dog was bathed and groomed in the morning and then an unknown amount of hours later the owner applied FRONTLINE PLUS DOG 5-22 LBS (P61304) 1 vial to the skin between the shoulder blades. 14 May 2019: Owner found alive and attached tick on dog's forehead and removed it. There is one other dog in the home who is treated with the product and does not have ticks. The dogs only go outside for short potty breaks in a small grassy fenced in area. The owner has been using the product on the dogs seasonally, March through November for an unknown amount of time. No further medical information expected.
31-May-2019	UAE; 19US030491; PA; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 25 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Phenobarbital; **Route:** Topical / Cutaneous	27-May-2019	27-May-2019	0 Day(s)	D-B	Suspected Adverse Event: On 31 May 2019, the owner reported the following event for a 4 years old*, 25 pounds, Spayed female, Shih Tzu. 27 May 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (R62514BL) was applied between the shoulder blades, by the pet owner. 3 hours later the dog started to have seizures, vomiting and heavy panting. 30 May 2019: The dog present to clinic and unknown care was given. The veterinarian prescribed phenobarbital. The dog started the medication but stopped eating after receiving it. 31 May 2019: The symptoms are still ongoing but dog is now in

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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?: Yes					pain. No further medical information is expected.
31-May-2019	UAE; 19US030520; GA; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Month(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-May-2019	21-May-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the owner reported the following event for Lucky, 8 months old*, 45 pounds, Neutered male, Medium crossbred (10-20 kg). 20 May 2019: The first vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades, by the pet owner. 21 May 2019: The dog had small amount of fleas. The dog has not been bathed or gone swimming. The dog does not have any skin issues. The owner is not seeing any flea activity in the home. The dog goes outside in an apartment complex for bathroom breaks. There is 1 cat in the home that is on FRONTLINE also with case 19US030594. No further medical information is expected. UPDATE 18 Jun 2019: Owner called to update. 18 Jun 2019: Owner called to inform us that the animal is still covered in fleas as of this day. No further information expected.
31-May-2019	UAE; 19US030523; NJ; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** - **Age:** 1.00 Year(s) **Weight:** 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	17-Apr-2019	24-May-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the animal owner reported the following event for Eve, a 1 year old*, 70.0 pound, intact non-pregnant non-lactating female German Shepherd Dog. 17 May 2019: She received FRONTLINE PLUS 45-88 LBS (S62202AX) one dose applied topically monthly. 24 May 2019*: The owner noticed fleas and she was pruritic. The dog does frequent the garden, under the porch, dog parks, groomers, and pet stores. She has not presented to the veterinary clinic. No treatments have been performed. Her current condition is ongoing. She had received FRONTLINE PLUS once previously on 17 Apr 2019 for the first time with no adverse effects noted. There is one other canine in the house hold that is on Advantage and one feline in the household that is on FRONTLINE PLUS CATS (R4106AW) with no fleas seen. No further medical information expected.
31-May-2019	UAE; 19US030524; AZ; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 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?:** Unknown to Company	23-May-2019	26-May-2019	3 Day(s)	D-D	Suspected Adverse Event: On 31 May 2019, the owner reported the following event for Dublin, an approx. 6 year old, 65 pound, neutered male, large crossbreed canine. 23 May 2019: Started on 1 dose of an unknown presentation of FRONTLINE DOG 45-88 LBS (product unsubstantiated) (lot unknown) topically by boarding facility staff. 26 May 2019: The owner picked up the dog and on the ride home he seemed nauseous. 28 May 2019: The dog started vomiting every time he ate or drank. The dog was not seen by a veterinarian or given any treatment. The symptom are ongoing. No further medical information expected.
31-May-2019	UAE; 19US030531; AL; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** -	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products**	28-May-2019	30-May-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, a pet owner reported the following event for Nala, a 3 year old, 10* pound, intact female Domestic Longhair. 4 Jan 2019*: The cat began receiving FRONTLINE PLUS CATS (S41108AW) monthly with a 3 pack purchased on 28 May 2019. 28 May 2019: The most recent dose was applied topically at the

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		Age: 3.00 Year(s) **Weight:** 10 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					base of the neck between the shoulder blades. That night the pet owner noticed dead fleas on the floor. 30 May 2019: The pet owner noticed flea dirt on the cat's head and saw approximately 20 live fleas on the cat. There are 2 other cats in the home that are on FRONTLINE. The cat is an indoor cat but has recently been sneaking outside when the owner has opened the door. The cat does not get baths and does not have any skin issues. The owner is getting bit by the fleas and has been moping the floor but not vacuuming. No further medical information expected.
31-May-2019	UAE; 19US030543; IN; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 16 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-May-2019	28-May-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 31 May 2019, a pet owner reported the following event for Booey, a 4 year old, 16* pound, neutered male Domestic Shorthair. 27 May 2019: The cat received 1 application of FRONTLINE PLUS CATS (R41206AW) topically between the shoulder blades. 28 May 2019*: The pet owner noticed that the cat's skin was pink where the FRONTLINE was applied. 29 May 2019: The pet owner noticed that the hair is missing and there appears to be burn marks where the FRONTLINE was applied. The cat has not presented to the clinic and no treatments have been initiated. The cat has previously received FRONTLINE during the summer months since 2017* without any adverse events noted. No further medical information expected.
31-May-2019	UAE; 19US030562; KS; U.S.A	**Species:** Canine **Breed:** Basset Hound **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 55 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?:** No (Overdose)	Apr-2019*	24-May-2019	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 May 2019, the pet owner reported the following event for Baby a female spayed, 12 pound, 16 year old, Dachshund (miniature). Unknown dates: The pet owner has given Baby aspirin for heart murmur. 24 May 2019: The pet owner noticed 15+ fleas on Baby. 27 May 2019: The pet owner bathed Baby with Dawn dish soap. 29 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (S63106AX) topically to skin between the shoulder blades of Baby monthly on year round basis with 15+ fleas. 30 May 2019: The pet owner continued to see 15+ fleas. 31 May 2019: Baby was in good health at time of application. Baby was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen any fleas in the home. Baby has no history of skin problems or any other issues with topical treatments. Baby has not had flea problem before in the past. Baby has not received any other topical treatments. Baby is indoors and outside in fenced yard. The current status of Baby is unknown. Baby shares FRONTLINE PLUS DOG 45-88 LBS with 3 other dogs in home with flea issues. Baby also share home with 2 other cats that are treated with FRONTLINE PLUS CATS with no flea issues. No further medical information.
31-May-2019	UAE; 19US030592; MI; U.S.A	**Species:** Canine **Breed:** Collie **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 54 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	30-Apr-2019	17-May-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the pet owner reported the following event for Nessie, a 5 year old, spayed female, Collie 30 Apr 2019: Dog received 1 dose of FRONTLINE PLUS DOG 45-88 LBS (P61903AR) (FL) topically in an unknown manner. 17 May 2019: Owner found an engorged tick. The tick was removed. The dog is out daily in wooded areas. The owner was concerned if the tick was supposed to fall off the dog at any point.

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						Route: Topical / Cutaneous **Was the product used ok?:** Unknown to Company					No further medical information expected.
31-May-2019	UAE; 19US030594; GA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 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	20-May-2019	21-May-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the owner reported the following event for Dela, 4 years old*, 9 pounds*, Spayed female, Domestic Longhair (crossbred). 20 May 2019: The first vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades, by the pet owner. 21 May 2019: The cat had small amount of fleas. The cat has not been bathed or gone swimming. The cat does not have any skin issues. The owner is not seeing any flea activity in the home. The cat goes outside on a leash in an apartment complex for bathroom breaks. There is 1 dog in the home that is on FRONTLINE also with case 19US030520. No further medical information is expected. UPDATE 18 Jun 2019: Owner called to update. 18 Jun 2019: Owner called to inform us that the animal is still covered in fleas as of this day. No further information expected.
31-May-2019	UAE; 19US030617; TX; U.S.A	**Species:** Canine **Breed:** Chihuahua **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:** IVERMECTIN CHEWABLE 55MCG; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-May-2019*	19-May-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the pet owner reported the following event for Blue a female spayed, 19 pound, 7 year old, Chihuahua/ small crossbreed. Unknown dates: The pet owner administers unknown amount of HEARTGARD CHEWABLE (lot number unknown, expiration unknown) (product unsubstantiated) PO to Blue. 18 May 2019: The pet owner noticed 5-15* fleas on the body of Blue. The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S61718AL) topically to skin between the shoulder blades of Blue monthly on year round basis. 19 May 2019: The pet owner continued to see 15+ fleas on the body of Blue. 31 May 2019: Blue was in good health at time of application. Blue was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen any fleas in the home. Blue has no history of skin problems or any other issues with topical treatments. Blue has not had flea problem before in the past. Blue has not received any other topical treatments. Blue has not been bathed. Blue is indoors and outside in fenced yard. The current status of Blue is unknown. Blue shares home with one other dog in the home treated with FRONTLINE PLUS DOG 45-88 LBS (S62202AX) with case number 19US034051. No further medical information.
31-May-2019	UAE; 19US030666; IL; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Yellow) **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 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**	20-May-2019	22-May-2019*	2 Day(s)	D-D	Suspected Adverse Event: On 31 May 2019, the owner reported the following event for the Isabel, a 80 pound, 9 year old, female, neutered, Yellow Labrador Retriever. 20 May 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S61104AR) was applied topically in one location in-between the shoulder blades by the pet owner. 22 May 2019*: The owner noticed skin irritation at the application site. The pet was not presented to the clinic. The owner called the clinic and was recommend to use an unknown anti-septic spray in the area. The pet's symptoms are ongoing. The pet has used FRONTLINE

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						product used ok?: Yes					PLUS DOG 45-88 LBS in the past with no reactions on a year round basis since the pet was a puppy starting in 2010*. No further medical information expected at this time.
31-May-2019	UAE; 19US030697; LA; U.S.A	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 13.00 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	17-May-2019*	18-May-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the owner reported the following event for a 13 years old, 7 pounds, male , Poodle (all other signalments unknown). History: The dog has used FRONTLINE in the past but unsure of when. 17 May 2019*: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades, by the pet owner. 18 May 2019: The dog had a small amount of fleas. The dog has not been bathed or gone swimming. The dog does not have any skin issues. The owner is not seeing any indoor flea activity. The dog goes outside in a fenced in area for bathroom breaks. No further medical information is expected.
31-May-2019	UAE; 19US030698; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Neutered **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-May-2019*	31-May-2019*	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, a pet owner reported the following event for a male neutered canine of further unknown signalment. May 2019: The dog had skin issues and dermatitus, The owner applied FRONTLINE PLUS DOG (product unsubstantiated)(lot unkonwn). The dog is still scratching due to fleas and skin issues. It is unknown if there were fleas prior to applying FRONTLINE PLUS. The owner is bathing with a hydrating/medicated/anti-fungal shampoo. No further medical information expected.
31-May-2019	UAE; 19US030702; WI; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 18 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	04-May-2019	17-May-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the owner reported the following event for Loki, a 4 year old (born 1 Jul 2014), 18 pound, spayed female, Domestic Shorthair crossbreed feline. Mar 2015*: Started on monthly doses of FRONTLINE PLUS CATS (S40815AW) topically, between the shoulder blades, by the owner. 4 May 2019: Most recent dose of FRONTLINE was applied. 17 May 2019: The owner started finding ticks on the cat. The owner found approx. 20 ticks. The owner removed the ticks once observed. Some ticks were alive, most were attached, and some had blood. The cats is indoor/outdoor and is able to roam in tall grass, on trails, in bushes, and the woods. There is another cat that is not having any problems. No further medical information expected.
31-May-2019	UAE; 19US030708; CA; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 60 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown shampoo; **Route:** Topical / Cutaneous **Was the**	15-May-2018*	27-May-2019*	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the pet owner reported the following event for a 60 pound, Labrador Retriever of further unknown signalment. Unknown dates: The canine began receiving one vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) applied topically between the shoulder blades. A vial has since been applied monthly, year round. Additionally, the canine is bathed monthly on an unknown date with unknown shampoo. 2017*: The reporter and canine moved to a different area of California, closer to the beach. 15 Mar 2019* - 15 May 2019*: It's been atypically rainy. May 2019* (unknown date): The reporter observed a couple of

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						product used ok?: Yes					fleas and lots of flea dirt on the canine. Presently, the issue is ongoing, but it's unclear if any treatment has been administered. There is a second dog in the home who is also receiving FRONTLINE PLUS. A case was also reported for that dog. Please see 19US031262. No further medical information expected.
31-May-2019	UAE; 19US030714; TX; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 1.30 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Unknown pet shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jan-2018*	27-Apr-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the owner reported the following event for an unknown 1.3 year old, female feline, 8lb, all other signalment unknown. 27 April 2019: One vial of the FRONTLINE PLUS CATS (Lot unknown) was applied topically in between the shoulder blades by the owner. Small amount of fleas seen on the pet. 28 April 2019: A small amount of fleas were noticed on the pet. 21 May 2019: One vial of the FRONTLINE PLUS CATS (Lot unknown) was applied topically in between the shoulder blades by the owner.A small amount of fleas were noticed on the pet. 27 May 2019: One vial of the FRONTLINE PLUS CATS (Lot unknown) was applied topically in between the shoulder blades by the owner. 30 May 2019: The owner noticed a small amount of fleas. The pet is indoor mostly and goes outside on occasion. The pet has access to a fenced in yard, unknown if wildlife is seen in the area. This is the first time the owner has seen fleas on the pet since starting the product in 2018* on year round basis. No fleas have been seen within the home. There is a dog in the home using FRONTLINE GOLD DOG 5-22 LBS (PP27061) see additional case 19US030537.No further medical information is expected.
31-May-2019	UAE; 19US030716; CA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 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	11-Mar-2019	31-May-2019*	18 Days	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the pet owner reported the following event for Juney, a 5 year old (born 1 Mar 2014) 10 pound, spayed female Domestic Longhair. 11 Mar 2019: The owner observed approximately 5 fleas on the cat and purchased 3 doses of FRONTLINE PLUS FOR CATS (R41201AW). The product was applied topically between the shoulder blades on 11 Mar 2019, 11 Apr 2019 and 13 May 2019. 31 May 2019: The owner has continued to see approximately 5 fleas on the cat. The owner has taken the cat outside for short periods of time but has stopped since seeing fleas on the cat. The cat doe snot get bathed and there are no other animals in the home. No further medical information expected.
31-May-2019	UAE; 19US030737; PA; U.S.A	**Species:** Canine **Breed:** Cairn Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(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	17-Apr-2019	29-May-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, a pet owner reported the following event for Brownie, a 10 year old, intact female, 14 pound, Cairn Terrier mix. 17 Apr 2019 and 17 May 2019: The owner applied FRONTLINE PLUS DOGS 5-22 LBS (lot unknown) topically between the shoulder blades. 29 May 2019: The dog is scratching and the owner is seeing fleas and flea dirt on abdomen. There is a feline in the house (19US030738) that is having similar issues. Owner receptive to product education. No further medical information expected. UPDATE 9 Jul 2019: the owner applied the third vial on 18 Jun 2019, the issue is still ongoing. No further medical information expected.

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31-May-2019	UAE; 19US030738; PA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 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?:** No (Treatment / vaccination program not respected)	17-Apr-2019	17-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, a pet owner reported the following event for Maui, a 3 year old, 9 pound, spayed female Domestic Shorthair. 17 Apr 2019 and 17 May 2019: The owner applied FRONTLINE PLUS CATS (lot unknown) topically at the base of the neck. 17 May 2019: The owner still saw fleas after application. The owner reported pulling 2 fleas off every other day via flea comb. There is a canine in the house (19US030737) that is having similar issues. Owner receptive to product education. No further medical information expected. UPDATE 9 Jul 2019: the owner applied the third vial on 17 Jun 2019 and the issue peristed. No further medical information expected.
31-May-2019	UAE; 19US030745; NY; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 53 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-May-2019	24-May-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 31 May 2019, the pet owner reported the following event for Leo a male neutered, 53 pound, 8 year old, Large crossbreed. 23 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (S61101AR) topically to skin between the shoulder blades of Leo monthly during summer months. After approximately 24* hours post application the pet owner noticed Leo experience vomiting and diarrhea. 31 May 2019: Leo was in good health at time of application. Leo was not presented to veterinarian. Leo has not had any other products at the same time as the FRONTLINE PLUS DOG 45-88 LBS application. Leo does not have history of drug or vaccine reactions. Leo has had FRONTLINE prior to reaction in summer months. Leo is currently at home with ongoing issue. No further medical information
01-Jun-2019	UAE; 19US030762; OH; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 10 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	28-Feb-2019*	28-Feb-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the owner reported the following event for 3 cats approximately 10-15 pounds (signalment unknown). *Unknown date: One vial of FRONTLINE PLUS CATS (lot unknown) was topically applied to the skin between the shoulder blades to each cat. The cats are indoor and started to have a large number of fleas and the home became infested. The cats do not have any dry skin issues and have received FL in the past and had the same issue with fleas for the past few months this year. Cats are indoor only, it is unknown how long the cats have been treated with FL and if they are treated seasonally or year round and if fleas were seen prior to the application. No further information available.
01-Jun-2019	UAE; 19US030769; FL; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 11 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown shampoo; **Route:** Topical /	14-May-2019	31-May-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the owner reported the following event for Abigail, a 6 year old, 11 pound, spayed female Maltese/Poodle mix. 14 May 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (FL) (S61718AL) was applied to the skin between the shoulder blades . 31 May 2019: The dog had a large number of fleas, she was bathed with an unknown shampoo and majority of the fleas were removed. Owner started to see fleas on this date. The dog is treated with FL monthly year round and goes out daily for potty breaks and walks. There are not any fleas in the home. The dog is bathed once every 5 weeks with an unknown shampoo.

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						Cutaneous **Was the product used ok?:** Yes					No further information available.
03-Jun-2019	UAE; 19US030775; NJ; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various **Sex:** M **Sex qualifier:** Neutered **Age:** 2.50 Year(s) **Weight:** 5 - 12 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Hartz flea and tick shampoo; veterinary oatmeal shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-May-2018*	30-May-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the pet owner reported the following event for Oreo a male neutered, 12 pound, 7 year old, Chihuahua/ small crossbreed. The pet owner also reported the following event for Chopper, a male neutered, 2.5 year old, 5 pound, Chihuahua. 28 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (P61304) topically to skin between the shoulder blades of the dogs monthly on year round basis. 30 May 2019: The pet owner first noticed 1-5 fleas on the body of the dogs. 2 Jun 2019: The pet owner bathed dogs with Hartz flea and tick shampoo and Veterinary oatmeal shampoo. 3 Jun 2019: The dogs were in good health at time of application. The dogs were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. The dogs have no history of skin problems or any other issues with topical treatments.The dogs had flea problem before in the past and it resolved. The dogs have not received any other medications or topical treatments. The dogs are indoors and outside in fenced yard. The current status of the dogs are unknown. No further medical information.
03-Jun-2019	UAE; 19US030778; NY; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 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	15-Jan-2016	03-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On the 3 Jun 2019, a pet owner reported the following event for Bella, an 18 pound, 8 year old, spayed female, Yorkshire Terrier Mix. 15 Jan 2016: The dog started on monthly FRONTLINE PLUS DOG 5-22 LBS (S61203AX) with 1 dose applied topically between the shoulder blades. Apr 2019: The pet owner started seeing ticks on her dog. 18 May 2019: The most recent dose of FRONTLINE PLUS was applied topically between the shoulder blades. 3 Jun 2019: The pet owner saw 4 attached ticks on her dog that were still alive after she detached them from her dog. The dog has access to the backyard throughout the day for his potty breaks. The pet owner is not taking her dog on walks or to any dog parks. The pet owner is not seeing ticks inside her home she sees the ticks after her dog goes outside. The pet owner has 2 additional dogs in the home that are on the same size of FRONTLINE PLUS. The owner is also seeing ticks on them as well see case numbers: 19US30779 and 19US030781. No further medical information expected. UPDATE 14 Jun 2109: Upon further review the lot number in the narrative was corrected.
03-Jun-2019	UAE; 19US030779; NY; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 11.00 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	18-May-2019	03-Jun-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 3 Jun 2019, a pet owner reported the following event for Foxy, an 11 pound, 10 year old, spayed female, Yorkshire Terrier. 15 Jan 2016: The dog started on monthly FRONTLINE PLUS DOG 5-22 LBS (S61203AX) with 1 dose applied topically between the shoulder blades. Apr 2019: The pet owner started seeing ticks on her dog. 18 May 2019: The most recent dose of FRONTLINE PLUS was applied topically between the shoulder blades. 3 Jun 2019: The pet owner saw 2 attached ticks on her dog that

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						Was the product used ok?: Yes					were still alive after she detached them from her dog. The dog has access to the backyard throughout the day for his potty breaks. The pet owner is not taking her dog on walks or to any dog parks. The pet owner is not seeing ticks inside her home she sees the ticks after her dog goes outside. The pet owner has 2 additional dogs in the home that are on the same size of FRONTLINE PLUS. The owner is also seeing ticks on them as well see case numbers: 19US30778 and 19US030781. No further medical information expected.
03-Jun-2019	UAE; 19US030781; NY; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 7.00 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-May-2019	03-Jun-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 3 Jun 2019, a pet owner reported the following event for Weazy, a 7 pound, 7 year old, spayed female, Yorkshire Terrier. 15 Jan 2016: The dog started on monthly FRONTLINE PLUS DOG 5-22 LBS (S61203AX) with 1 dose applied topically between the shoulder blades. Apr 2019: The pet owner started seeing ticks on her dog. 18 May 2019: The most recent dose of FRONTLINE PLUS was applied topically between the shoulder blades. 3 Jun 2019: The pet owner saw 2 attached ticks on her dog that were still alive after she detached them from her dog. The dog has access to the backyard throughout the day for his potty breaks. The pet owner is not taking her dog on walks or to any dog parks. The pet owner is not seeing ticks inside her home she sees the ticks after her dog goes outside. The pet owner has 2 additional dogs in the home that are on the same size of FRONTLINE PLUS. The owner is also seeing ticks on them as well see case numbers: 19US30778 and 19US030779. No further medical information expected.
03-Jun-2019	UAE; 19US030789; KS; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 8 - 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	20-May-2019*	24-May-2019*	4 Day(s)	D-D	Suspected Adverse Event: On 3 Jun 2019, the pet owner reported the following event for Pinky, a 5 year old, 12 lb, intact female Pomeranian and Foxy, a 2 year old 8 lb intact female Hound Mix. 20 May 2019*: Both dogs received one dose of FRONTLINE PLUS DOG 5-22 LBS (P60208AL) (FL) topically between the shoulder blades. 24 May 2019*: Dogs began itching and scratching. The symptoms have continued to worsen as the days progressed. The dogs were not scratching prior to FL application. The veterinarian has not been contacted. The general health of the dogs in unknown. No further medical information expected.
03-Jun-2019	UAE; 19US030799; FL; U.S.A	**Species:** Canine **Breed:** Schnauzer (Miniature) **Sex:** M **Sex qualifier:** - **Age:** 5.00 Month(s) **Weight:** 15.0 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-D	Suspected Lack of Efficacy Claim: On 03 Jun 2019, the animal owner reported the following event for an unknown canine, 5 month old*, intact male Miniature Schnauzer. 30 May 2019: He began receiving FRONTLINE PLUS DOG 5-22 LBS (S61902AL) one dose topically between the shoulders for the first time. 31 May 2019: The owner noticed a moderate amount of fleas. The dog yard is primarily sand. He has not presented to the veterinary clinic. No treatments have been performed. His current condition is ongoing. There are three other canines in the household which received a different sized FRONTLINE PLUS one dose applied topically between the shoulders on 30 May 2019. The owner is not seeing fleas on the other three canines. No further medical information expected.

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03-Jun-2019	UAE; 19US030818; FL; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 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?:** Unknown to Company	17-Mar-2019	03-Jun-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 03 Jun 2019 an animal owner reported the following event in Allie, a 9 year old, 12 pound, female spayed Shih Tzu. 17 Mar 2019: The canine started receiving monthly doses of FRONTLINE PLUS DOGS 5-22 LB (Lot P62719B) to prevent flea and tick infestation. No fleas seen at time of application. 17 May 2019: The canine was bathed with a pet shampoo. 18 May 2019: The canine received a dose of FRONTLINE PLUS. 03 Jun 2019: The animal owner is seeing fleas and flea dirt at the base of the tail. There are 2 other canines in the home that are reported in cases 19US030843 and 19US030844. The animal owner has treated the yard. No further information provided nor expected.
03-Jun-2019	UAE; 19US030825; MD; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 35.0 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-Apr-2018*	03-Apr-2018*	2 Day(s)	D-B	Suspected Adverse Event: On 03 Jun 2019, the animal owner reported the following event for Joey, a 5 year old* (born 04 Jul 2012*), 35.0 pound, neutered male Labrador Retriever Poodle Mix. Apr 2018*: He received FRONTLINE PLUS 23-44 LBS (M62016) one dose applied topically between the shoulders for the first time. He began experiencing seizure activity approximately 48 hours post application. The activity lasted approximately three minutes during which he fell over, lost control of bladder, hypersalivated, and vomited. He appeared to be post-ictal for approximately two minutes. He presented to the veterinary clinic. Blood work was performed with no abnormalities noted. No treatments were initiated. He recovered an unknown time post symptom onset. He subsequently had a similar adverse event after application of FRONTLINE PLUS (see case 19US03830). No further medical information expected.
03-Jun-2019	UAE; 19US030830; MD; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 35.0 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	02-Jun-2019	03-Jun-2019	1 Day(s)	D-B	Suspected Adverse Event: On 03 Jun 2019, the animal owner reported the following event for Joey, a 6 year old (born 04 Jul 2012*), 35.0 pound, neutered male Labrador Retriever Poodle Mix. 02 Jun 2019: He received FRONTLINE PLUS 23-44 LBS (M62016) one dose applied topically between the shoulders. 03 Jun 2019: He began experiencing seizure. The activity lasted approximately one to two minutes during which he lost control of bladder, inability to stand, hypersalivated, and vomited. He appeared to be post-ictal for approximately five minutes. He has not presented to the veterinary clinic. No treatments have been initiated. His current condition is ongoing, improving. He previously received an application of FRONTLINE PLUS Apr 2018* with adverse effects noted (see case 19US030825) and on 02 May 2019 with no adverse effects noted. No further medical information expected.
03-Jun-2019	UAE; 19US030837; TN; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 16.00 Year(s) **Weight:** 6.4 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Methimazole; **Route:** Topical / Cutaneous	18-May-2019	18-May-2019	0 Day(s)	D-C	Suspected Adverse Event: On 3 Jun 2019, the veterinary technician reported the following event for Ojimwa, a 16 year old (born 12 Mar 2003), 6.4 pound, spayed female, Domestic Longhair crossbreed feline. Mar 2019*: Started on 2.5 mg of Methimazole twice a day for hyperthyroidism. 18 May 2019: Started on FRONTLINE (product unsubstantiated) (lot unknown) topically, between the shoulder blades, by the owner. The cat licked the product. The cat started having diarrhea. Unknown date: the cat was examined by the veterinarian. A CBC was performed with the following abnormal results: low potassium

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						Was the product used ok?: Yes					and high glucose. The cat was treated with Albon and Metronidazole. The symptoms are ongoing. No further medical information expected.
03-Jun-2019	UAE; 19US030843; FL; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** - **Age:** 3.00 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	17-Mar-2019	03-Jun-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 03 Jun 2019 an animal owner reported the following event in Willie, a 10 pound, 3 year old, intact male, Chihuahua. 17 Mar 2019: The canine started receiving monthly doses of FRONTLINE PLUS DOGS 5-22 LB (Lot P62719B) to prevent flea and tick infestation. No fleas seen at time of application. 17 May 2019: The canine was bathed with a pet shampoo. 18 May 2019: The canine received a dose of FRONTLINE PLUS. 03 Jun 2019: The animal owner is seeing fleas and flea dirt at the base of the tail. There are 2 other canines in the home that are reported in cases 19US030844 and 19US030818. The animal owner has treated the yard. No further information provided nor expected.
03-Jun-2019	UAE; 19US030844; FL; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 3.50 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	17-Mar-2019	03-Jun-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 03 Jun 2019 an animal owner reported the following event in Caleesi, a 3.5 year old, 12 pound, female spayed, Chihuahua mix. 17 Mar 2019: The canine started receiving monthly doses of FRONTLINE PLUS DOGS 5-22 LB (Lot P62719B) to prevent flea and tick infestation. No fleas seen at time of application. 17 May 2019: The canine was bathed with a pet shampoo. 18 May 2019: The canine received a dose of FRONTLINE PLUS. 03 Jun 2019: The animal owner is seeing fleas and flea dirt at the base of the tail. There are 2 other canines in the home that are reported in cases 19US030818 and 19US030844. The animal owner has treated the yard. No further information provided nor expected.
03-Jun-2019	UAE; 19US030873; VA; U.S.A	**Species:** Canine **Breed:** Chihuahua **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	15-May-2011*	22-May-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019 the pet owner reported the following event via mail for two Chihuahuas of unknown signalment. 15 May 2019: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (R60830AL), unknown dose, route, or application site to the two canines. It is unknown if there were fleas on the canines prior to application. 27 May 2019*: The pet owner reported seeing an unknown number of fleas on the two canines. It is unknown what outdoor areas the pets have access to or where they spend the majority of the time. It is also unknown if the pet owner is currently seeing fleas. There are two other canines and two cats in the household that are on FRONTLINE PLUS that are not exhibiting fleas. No further information is available at this time. UPDATE 12 Jun 2019: Per owner phone call, The event was for Champ, a 9 year old, 10 pound, male neutered, Chihuahua. Tyson, a 8 year old, 10 pound, male neutered, Chihuahua. Emma, a 8 year old, 12 pound, intact female, Chihuahua. 15 May 2019: The owner applied the FRONTLINE PLUS as directed by the box. 22 May 2019*: The owner was seeing fleas on the dogs. The dogs do go out in the yard to play and potty from time to time. While they gets bathed it is only when needed, and the owner

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											waits 24 hours after use of FRONTLINE. The owner uses a scented shampoo for bathing, and flea combs the animals daily. The owner also treats the inside of the house with baking soda followed by vacuuming. The animals are itching, but the owner stated that started with the fleas. She is seeing about 3 to 10 plus fleas on the animals daily. Champ, Emma, and Tyson have been using FRONTLINE with no issues since 2011*. They have had a reaction to Zodiac that caused severe itching, but this reaction stopped after switching off that product. The other Chihuahua in the house also had a similar event and a case was reported at this time, see 19US034564. No further information is expected.
03-Jun-2019	UAE; 19US030886; OH; U.S.A	**Species:** Feline **Breed:** Ragdoll **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 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 / Cutaneous **Was the product used ok?:** Yes	27-May-2019	01-Jun-2019*	5 Day(s)	D-D	Suspected Adverse Event: On 3 Jun 2019 the pet owner reported the following event for Indy, a 9 year old (born *1 Nov 2009), 11 pound, neutered male Ragdoll. 27 May 2019: The pet owner applied FRONTLINE PLUS CATS (lot and expiration unknown), 1 dose, topically, intrascapular for the first time. 1 Jun 2019*: The feline began exhibiting generalized bleeding sores and pruritus. Currently, the feline's health status is unchanged and he has not received treatment. No further medical information is expected.
03-Jun-2019	UAE; 19US030888; -; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 42 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-2018*	20-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, a pet owner reported the following event for Happy, a 4 year old, 42 pound, neutered male Medium crossbred canine. 20 Apr 2019*: The pet owner noticed 2-3 live fleas on the dog. 1 May 2019*: The dog received 1 application of FRONTLINE PLUS DOG 23-44 LBS (R60516AL) topically between the shoulder blades. 15 May 2019*: The pet owner noticed 2-3 live fleas on the dog and has continued to see live fleas daily. 1 Jun 2019: The most recent application of FRONTLINE was applied and then 2 hours later the dog jumped into the pool and was in there for several hours. The pet owner has been using FRONTLINE year round since Jan 2018* and has never had a problem with fleas in the past. The pet owner is not seeing any fleas in the house but has been using an unknown flea spray inside the home. He also stated that there are a lot of stray cats around. No further medical information expected.
03-Jun-2019	UAE; 19US030893; -; 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	30-May-2019	03-Jun-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the owner reported the following event for a canine with unknown signalment. 30 May 2019: The most recent dose of FRONTLINE PLUS DOG (product unsubstantiated)(lot unknown) via an unknown route and location. 3 Jun 2019*: The owner is seeing a low amount of fleas located at the base of the tail. It is unknown if pet has received FRONTLINE in the past. His lifestyle and environment is unknown. The owner stated that fleas have not been seen in the home. No further information a this time.

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03-Jun-2019	UAE; 19US030895; WI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **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 ok?:** Yes	02-May-2019	02-Jun-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 03 Jun 2019, Animal owner reported the following event for Winston, a 2 year old, 50 pound, neutered male, mixed breed. Oct 2018, Nov 2018, Apr 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (Lot unknown) topically to the back of the neck. 02 May 2019: Last dose was applied. 02 Jun 2019: The pet owner found an engorged tick on the right flank. The tick was alive and removed. The owner did not take the tick to the veterinarian to be identified and has not seen any further ticks. The dog is mostly indoors along with two other housemates who do not share the same weight category. The dog has not been bathed. No further information expected.
03-Jun-2019	UAE; 19US030903; -; 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:** unknown **Was the product used ok?:** Unknown to Company	17-May-2019	03-Jun-2019*	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the owner reported the following event for 4 canines of unknown signalment. Unknown Date 2017*: The owner started the dogs on FRONTLINE PLUS (product unsubstantiated)(lot unknown). 17 May 2019: The owner applied the most recent dose of FRONTLINE PLUS to the dogs via unknown route and location. 3 Jun 2019*: The owner noticed increased scratching and the pets are heavily infested with fleas. They do spend some time outdoors. No further information at this time.
03-Jun-2019	UAE; 19US030908; CA; 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-Feb-2009	03-Jun-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019 the pet owner reported the following event for a canine of unknown signalment. 1 Jun 2009*: Started on FRONTLINE PLUS DOG 23-44 LBS (lot and expiration unknown), 1 dose, topically, intrascapular seasonally, from June to September of each year. 1 Feb 2019: The pet owner began seeing an unknown number of fleas on the canine and began applying the product once monthly. 1 Jun 2019: The most recent dose was applied. 3 Jun 2019: Currently, the pet owner is still seeing an unknown number of fleas on the canine. The canine has access to the yard and spends the majority of the time indoors. There are no other pets in the home. No further medical information is expected.
03-Jun-2019	UAE; 19US030944; FL; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** - **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 ok?:** Yes	01-Mar-2019	01-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the pet owner reported the following event for a 5 pound, male neutered, Domestic Longhair (Crossbreed). 1 Mar 2019: The cat was having an issue with fleas a 6 pack of FRONTLINE was purchased. The owner began applying 1 vial of FRONTLINE PLUS CATS (S40901AW) in one area between the shoulder blades. 1 May 2019: 1 vial was applied to the cat. The owner has been seeing small amount of fleas on the dog everyday since the application. The cat is indoors only. There are no fleas in the home biting the humans. There are no other pets in the home. The cat has not had a bath and has no history of skin issues. No further medical information is expected.

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03-Jun-2019	UAE; 19US030953; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 2.50 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	01-Jan-2016*	02-Jun-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim:On 3 Jun 2019, the owner reported the following event for an unknown 2.5 year old, canine, weighing 24 pounds, all other signalment unknown. 20 May 2019: One vial of the FRONTLINE PLUS DOG 23-44 LBS (R61915AL) was applied topically in between the shoulder blades by the owner. 2 Jun 2019: The owner noticed ticks on the pet large and engorged. The pet is indoor mostly and goes outside for potty breaks. The pet has access to an open yard of 5 acres were no wildlife is seen. This is the first time the owner has ticks on the pet. The owner has used FRONTLINE since 2016* on a year round basis. There is another pet in the home having issues with ticks see additional case 19US031195. No further medical information is expected.
03-Jun-2019	UAE; 19US030966; OK; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 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	16-May-2019	17-May-2019	1 Day(s)	D-D	Suspected Adverse Event: On the 3 Jun 2019, a pet owner reported the following event for Romeo, a 60 pound, 9 year old, neutered male, Australian Shepherd. 16 May 2011: The dog started on monthly FRONTLINE PLUS 45-88 LBS (unknown lot number, package unavailable) with 1 dose applied topically between the shoulder blades and down the back, by the pet owner. 16 May 2019: The most recent dose of FRONTLINE PLUS was applied by the pet owner. 17 May 2019: The pet owner noticed that the dog had a scab and was scratching in the middle of the back and there was a round patch of alopecia around the scab, where the FRONTLINE PLUS had come into contact with the skin after she applied it. 21 May 2019: The dog recovered in full. The dog did not visit his veterinarian for this reaction and did not receive any treatment. No further medical information expected.
03-Jun-2019	UAE; 19US030969; KY; U.S.A	**Species:** Feline **Breed:** American Shorthair **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 12 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Cat Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	26-May-2019	26-May-2019	0 Day(s)	D-B	Suspected Adverse Event and Suspected Lack of Efficacy Claim: On 3 Jun 2019 the pet owner reported the following event for Foof a 5 year old, 12 pound, female spayed American Shorthair. *19 May 2019: The owner bathed the cat with an unknown cat shampoo because the owner had been seeing an unknown amount of fleas for an unknown amount of time. 26 May 2019: The owner applied 1 vial of African labeled FRONTLINE PLUS CATS (S40705B) to the skin between the shoulder blades for the first time. About 30 minutes later the cat began pacing and meowing frantically, and went into a seizure that lasted less than 1 minute. The cat lost her bladder and the owner believes it was a grand mal seizure. The owner bathed the cat in Dawn dish soap for 20-30 minutes. The cat has repeated these episodes 8 times since application. 31 May 2019: The cat had the most recent episode and presented to the vet clinic and was treated with Diazepam and capstar. The pacing and meowing is ongoing. The cat still has an unknown amount of fleas. There is 1 other indoor only cat in the household treated with the same product that still has fleas and exhibited symptoms with case number 19US030991 and 8 other indoor only cats treated with the same product with fleas and not symptoms with case number 19US030994 and 1 dog treated with 2 vials of the same product still seeing fleas with no symptoms with case number 19US031019. The cat is indoor only. The owner is seeing indoor flea activity. No further medical information expected. UPDATE 5 JUN 2019: The following information was received from the owner via email.

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											3 Jun 2019: The owner noticed a wound at the application site that looks like a chemical burn between 1cm to 1in in size. 4 of the other cats have a similar wound with case number 19US031788. No further medical information expected. UPDATE 21 Jun 2019: After further review, lack of efficacy was added to VeDDRA.
03-Jun-2019	UAE; 19US030986; -; 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:** unknown **Was the product used ok?:** Unknown to Company	01-Jun-2019*	03-Jun-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the owner reported the following event for 3 canines of unknown signalment. Jun 2019*: Each dog received 1 dose of FRONTLINE PLUS DOG 45-88 LBS (Lot Unknown) via unknown route and location. 3 Jun 2019*: The owner is still seeing a decent amount of fleas on all 3 dogs. The dog's lifestyle and environment is unknown. This is their second dose that has been applied; the dogs started on FRONTLINE in May 2019*. It is unknown if fleas were seen prior to product use as owner was combative and did not wish to give any details. No further information at this time.
03-Jun-2019	UAE; 19US030991; KY; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 9 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Cat Shampoo; Phenobarbital; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	26-May-2019	26-May-2019	0 Day(s)	D-C	Suspected Adverse Event and Suspected Lack of Efficacy Claim: On 3 Jun 2019 the pet owner reported the following event for Tribble an 11 year old, *9 pound, male neutered Domestic Longhair. *2017: The cat was started on Phenobarbital after having seizure episodes following the use of Sargent's Silver flea and tick preventative. The cat has periodic mild seizures at an unknown frequency. *19 May 2019: The owner bathed the cat with an unknown cat shampoo because the owner had been seeing an unknown amount of fleas for an unknown amount of time. 26 May 2019: The owner applied 1 vial of African labeled FRONTLINE PLUS CATS (S40705B) to the skin between the shoulder blades for the first time. About 30 minutes later the cat had a mild seizure, the owner describes the seizure as ticks/tremors that lasted less than 1 minute. The owner bathed the cat in Dawn dish soap for 20-30 minutes. The cat has remained wobbly since the initial seizure activity. The cat did not present to the vet clinic and symptoms are ongoing. The cat still has an unknown amount of fleas. There is 1 other indoor only cat in the household treated with the same product that still has fleas and exhibited symptoms with case number 19US030969 and 8 other indoor only cats treated with the same product with fleas and not symptoms with case number 19US030994 and 1 dog treated with 2 vials of the same product still seeing fleas with no symptoms with case number 19US031019. The cat is indoor only. The owner is seeing indoor flea activity. No further medical information expected. UPDATE 5 JUN 2019: The following information was received from the owner via email. 3 Jun 2019: 4 of the other cats in the household experienced a suspected adverse event with case 19US031788. No further medical information expected.
03-Jun-2019	UAE; 19US031006; MS; U.S.A	**Species:** Feline **Breed:** Manx **Sex:** F **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	30-Apr-2019	14-May-2019*	N/A	D-D	Suspected Adverse Event: On 3 June 2019, the owner reported the following event for Grace, 6 years old, 8 pounds*, Spayed female, Manx. 30 Apr 2019: One vial of FRONTLINE PLUS CATS (S40502AX)

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		Neutered **Age:** 6.00 Year(s) **Weight:** 8 lbs				12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					was applied between the shoulder blades, by the pet owner. 14 May 2019*: The cat started to extremely itch. 30 May 2019: Another dose of the FRONTLINE was applied to the cat. The itching still constant. No fleas were seen on cat. Some particles that looked like grains of sand were seen on the cat. There is 1 other cat in the home sharing the FRONTLINE PLUS as well with case 19US031109. No further medical information is expected.
03-Jun-2019	UAE; 19US031009; -; 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:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2019*	03-Jun-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the pet owner reported the following event for a feline of unknown signalment. 1 Jun 2019*: The cat was given a dose of FRONTLINE PLUS CATS (lot unknown). 3 Jun 2019*: The cat had fleas. The other unknown number of cats do not have fleas and there are no fleas in the home. The cats do go out on the patio. The cat has been receiving the FRONTLINE every month for an unknown amount of time and has not had fleas prior. No further medical information expected.
03-Jun-2019	UAE; 19US031010; AL; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.50 Year(s) **Weight:** 6 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	26-Feb-2019	03-Jun-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 3 Jun 2019, a pet owner reported the following event for Ginger, a 6 pound, 1.5 year old, spayed female, Domestic Shorthair. 26 Feb 2019: The cat started on monthly FRONTLINE PLUS CATS (S403018X), with 1 dose applied topically between the shoulder blades by the pet owner seasonally. The pet owner has a total of 2 cats and they are both on FRONTLINE PLUS. 5 May 2019: The pet owner started seeing fleas on 1 cat. 26 May 2019: The most recent dose was applied topically by the pet owner. 3 Jun 2019: The pet owner is still seeing fleas on her cat. Her cat is indoor/outdoor. She has access to the garage and that is where she spends the majority of the time and the pet owner is seeing the fleas in that area, not inside her home. The cat has a moderate amount of fleas (5-15 fleas daily). The issue is ongoing. No further medical information expected.
03-Jun-2019	UAE; 19US031015; PA; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **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-Jan-2017*	01-Jan-2017*	0 Day(s)	D-A	Suspected Adverse Event: On 03 Jun 2019, the animal owner reported the following event for an unknown canine, a 13 year old*, unknown weight, neutered male German Shepherd Dog. Unknown date: The canine had FRONTLINE PLUS (unsubstantiated) (lot and expiration unknown) one dose applied topically once down the back for the first time. An unknown time post application the owner noticed he had sores along his back. It is unknown if he presented to the veterinary clinic. It is unknown if any treatments were administered. It is unknown if his symptoms completed resolved. Jun 2017*: An unknown time post the application, he was humanely euthanized for unknown unrelated issues. The product was never applied subsequently. He did have a pertinent medical history of atopic dermatitis. This is the extent of information known as the owner refused to complete reporting. No further information expected.
03-Jun-2019	UAE;	**Species:** Canine	1	1	0	**Product used:**	26-May-2019	27-May-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019 the pet owner

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	19US031019; KY; U.S.A	**Breed:** Small crossbred (<10 Kg) **Sex:** U **Sex qualifier:** Neutered **Age:** - **Weight:** 23 lbs				FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Dog Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)					reported the following event for an unknown 23 pound neutered small crossbred canine. All other signalments are unknown *19 May 2019: The owner bathed the dog with an unknown dog shampoo because the owner had been seeing an unknown amount of fleas for an unknown amount of time. 26 May 2019: The owner applied 1 vial of African labeled FRONTLINE PLUS CATS (S40705B) to the skin between the shoulder blades for the first time. 27 May 2019: The dog still had an unknown amount of fleas present. There are 2 other indoor only cat in the household treated with the same product that still have fleas and exhibited symptoms with case number 19US030969 and 19US030991 and 8 indoor only cats treated with the same product still seeing fleas with no symptoms with case number 19US030994. The dog has access to a gravel driveway. The owner is seeing indoor flea activity. No further medical information expected. UPDATE 5 JUN 2019: The following information was received from the owner via email. 3 Jun 2019: 4 of the other cats in the household experienced a suspected adverse event with case 19US031788. No further medical information expected.
02-Jun-2019	UAE; 19US031020; OH; U.S.A	**Species:** Feline **Breed:** Maine Coon Cat **Sex:** F **Sex qualifier:** Unknown **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?:** Unknown to Company	02-Jun-2019*	02-Jun-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 2 Jun 2019, the following event was reported to Safety Call International (SCI) by the pet owner for a 10 pound, 2 year old (born *1 Jan 2017), female of unknown reproductive status Maine Coon Cat. 2 Jun 2019*: The pet owner applied FRONTLINE PLUS CATS (product unsubstantiated) (lot and expiration unknown),1 dose, topically, unknown application site. It is unknown if the feline had received the product previously. At an unknown time following application on the same date the feline began grooming the application site and began exhibiting hypersalivation at an unknown time later. The pet owner bathed the feline with an unknown brand of liquid dish soap. Currently, the feline's health status is unknown. No further medical information is expected.
03-Jun-2019	UAE; 19US031025; CA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 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-May-2019*	27-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, a pet owner reported the following event for Rocky, an approximately 7 year old, 15* pound, neutered male Domestic Longhair. 2017*: The cat receives the contents of 1 vial of FRONTLINE PLUS CATS (S41202AX) topically between the shoulder blades monthly, with 8 doses purchased on 27 Apr 2019 from Costco. 1 May 2019*: The cat received 1 application of FRONTLINE. 27 May 2019*: The pet owner noticed 1 live tick on the cat but it is unknown if it was attached. The pet owner removed it. 1 Jun 2019*: The most recent application was applied. 3 Jun 2019*: The pet owner noticed that there were an unknown amount of live fleas on the cat's face. He is seeing fleas in the house on the bed that are alive but he is not getting bit. The pet owner usually applies FRONTLINE every 30 days year round and has never had an issue with fleas in the past. The cat is indoor/outdoor and the yard is not fenced. There are no other pets in the home. No further medical information expected.
03-Jun-2019	UAE; 19US031035; WI; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20	1	1	0	**Product used:** FIPRONIL 10%/S	30-May-2019	03-Jun-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019 the pet owner reported the following event for an unknown 50 pound Large crossbred (>20kg) canine. All other signalments are unknown.

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		Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 50 lbs				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					30 May 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (R62301) to the skin between the shoulder blades for the first time. 3 Jun 2019: The dog was bathed with an unknown shampoo at groomer and had 19 ticks alive and embedded. Some ticks were engorged but not all. Groomer removed all ticks There are no other pets in the home. The dog has free access to fields of tall grass, but stays out of the woods. Owner has not noticed the ticks. No further medical information expected.
03-Jun-2019	UAE; 19US031046; CA; U.S.A	**Species:** Canine **Breed:** Belgian Malinois **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:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	Sep-2018*	01-Mar-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the pet owner reported the following event for Shayla, a 5 year old, 65 lb., spayed female, Belgian Malinois. Sep 2018*: Pet owner began making applications of FRONTLNE PLUS DOG 45-88 LBS (R61513AR) (FL) topically in an unknown manner. 1 Mar 2019*: Dog received most recent application of FL. Pet owner stated that during the course of use she continued to find fleas on the dog. The dog was bathed an unknown number of times with an unknown shampoo. The dog was indoor/outdoor and the pet owner was finding 10+ fleas at a time while brushing. The outdoor area was treated as well. The pet owner has since switched to another product. No further medical information expected.
03-Jun-2019	UAE; 19US031092; VA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 16.00 Year(s) **Weight:** 12 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	13-Dec-2018*	13-May-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the pet owner reported the following event for Tiger, a 12 pound, 16 year old, male neutered, Domestic Shorthair (Crossbreed). Dec 2018: The cat was having an issue with fleas. The owner purchased an 8 pack of FRONTLINE PLUS CATS (S40301AX). 1 vial was applied to the cat in one area between the shoulder blades monthly. 13 May 2019*: 1 vial of FRONTLINE PLUS CATS was applied to the cat. The owner has been seeing a large amount of fleas on the cat every day since the application. The cats is indoor/outdoor. There are fleas present in the home biting the humans. The cat has no history of skin issues and has not had a bath recently. There are 3 other cats in the home having an issue with fleas signalments unknown. No further medical information expected.
03-Jun-2019	UAE; 19US031109; MS; U.S.A	**Species:** Feline **Breed:** Manx **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 7.000 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	30-Apr-2019	14-May-2019*	N/A	D-D	Suspected Adverse Event: On 3 June 2019, the owner reported the following event for Maggie, 6 years old, 7 pounds*, Spayed female, Manx. 30 Apr 2019: One vial of FRONTLINE PLUS CATS (S40502AX) was applied between the shoulder blades, by the pet owner. 14 May 2019*: The cat started to extremely itch. 30 May 2019: Another dose of the FRONTLINE was applied to the cat. The itching still constant. No fleas were seen on cat. Some particles that looked like grains of sand were seen on the cat. There is 1 other cat in the home sharing the FRONTLINE PLUS as well with case 19US031006. No further medical information is expected.
03-Jun-2019	UAE; 19US031121; FL; U.S.A	**Species:** Canine **Breed:** American Bully	1	1	0	**Product used:** FIPRONIL 10%/S	01-Jan-2017	01-Jun-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the owner reported the following event for Molly, 1 year old, 45 pound, spayed female, American Bulldog canine.

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		Sex: F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 45 lbs				METHOPRENE 9% SPOT ON **Other products used:** Dawn; Unknown dog shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					15 May 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades. 1 Jun 2019: The owner started to notice a large number of fleas on the pet. The pet also started itching. 2 Jun 2019: The owner bathed the pet with an unknown dog shampoo and Dawn. 3 Jun 2019: The flea issue and itching are still ongoing. The dog has access to a fenced in yard. The dog has received the FRONTLINE for the past few years with no issue. There are no other pets in the household. No further medical information is expected.
03-Jun-2019	UAE; 19US031122; NC; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** M **Sex qualifier:** - **Age:** 6.00 Year(s) **Weight:** 132 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-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, a pet owner reported the following event for Smoke, an approximately 6 year old, 132 pound, intact male Pit Bull. 1 Jun 2019: The dog received 1 application of FRONTLINE PLUS DOG 89-132 LBS (S62006AX) topically between the shoulder blades for the first time because the dog had fleas. Later on that day the dog was scratching and the pet owner noticed a moderate amount of fleas on the dog. The pet owner has continued to see fleas on the dog daily and the dog has continued to scratch. The pet owner is not getting bit but is seeing some live fleas on the bed. The yard is not fenced in and there are woods behind the house that the dog has access to. The pet owner stated that he has used FRONTLINE in the past on other dogs and has never had an issue with fleas. There is 1 other dog in the home that is on FRONTLINE and has fleas, see case 19US031658. No further medical information expected.
03-Jun-2019	UAE; 19US031137; CO; U.S.A	**Species:** Canine **Breed:** Fox Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 15.6 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	26-May-2019	26-May-2019	0 Day(s)	D-D	Suspected Adverse Event: On 3 Jun 2019 the veterinarian reported the following event for Bianca, a 13 year old (born 7 May 2006), 15.6 pound, spayed female Fox Terrier. 26 May 2019: The pet owner applied FRONTLINE PLUS DOG 0-22 LBS (lot and expiration unknown), 1 dose, topically, intrascapular for the first time. At an unknown time following application on the same date the canine began exhibiting pruritus and scratching at the application site. 27 May 2019: The pet owner bathed the canine with an unknown product. Currently, it is unknown if the reaction continues. The veterinarian has a high suspicion the product is responsible for the reaction. No further medical information is expected.
03-Jun-2019	UAE; 19US031154; NY; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 60 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 /	01-May-2019	03-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 3 June 2019, the owner reported the following event for 2 canines weighing 60 pounds each, other signalment unknown. 1 May 2019: One vial of the FRONTLINE PLUS DOG 45-88 LBS (S62111AL) was applied topically in between the shoulder blades by the owner. 2 May 2019*: The Owner noticed a small amount of ticks on the pet.The ticks were embedded and still alive but not engorged, and some were crawling on the dogs' coat. 31 May 2019: One vial of the FRONTLINE PLUS DOG 45-88 LBS (S62111AL) was applied topically as in between the shoulder blades by the owner. 3 June 2019: 2 more ticks were found on the pets. The dogs are indoor mostly and go outside for potty breaks and recreation within

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						vaccination program not respected)					an open yard. Wildlife has not been seen in the area. The owner applied the product twice in one month and continued to see ticks for 3 weeks after the first application. No further medical information is expected.
03-Jun-2019	UAE; 19US031159; CA; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 50 - 60 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	22-May-2016*	27-May-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the owner reported the following event for 3 Australian Shepherds, ranging from 50-60 pounds (all other signalments unknown). 22 May 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S61202AX) was applied between the shoulder blades. 27 May 2019: The owner found a large number of fleas on the dogs. The dogs also started itching. No fleas were noted in the household. 3 Jun 2019: The issue is still ongoing. The dog have access to a fenced in yard for potty breaks. The dogs have received the product monthly for the past few years (2017*) with no issue. There are 2 other dogs in the household also being treated and experiencing an issue (see case 19US031160). There are 3 cats in the household. Two of the cats are being treated with FRONTLINE and experiencing no issue the other cat is not being treated. No further medical information is expected.
03-Jun-2019	UAE; 19US031160; -; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 10 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	27-May-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the owner reported the following event for 2 Chihuahua canines, 10 pounds (all other signalments unknown). 22 May 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S60714AX) was applied between the shoulder blades. 27 May 2019: The owner found a large number of fleas on the dogs. The dogs also started itching. No fleas were noted in the household. 3 Jun 2019: The issue is still ongoing. The dog have access to a fenced in yard for potty breaks. The dogs have received the product monthly for the past few years (2017*) with no issue. There are 3 other dogs in the household also being treated and experiencing an issue (see case 19US031159). There are 3 cats in the household. Two of the cats are being treated with FRONTLINE and experiencing no issue the other cat is not being treated. No further medical information is expected.
03-Jun-2019	UAE; 19US031189; CA; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 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	30-Mar-2019	03-Jun-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the owner reported the following event for a 5 year old, 40 pound, neutered male, Large Crossbreed canine. Unknown date: The owner started to notice fleas on the dog. 30 Mar 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (S63019AL) was applied between the shoulder blades for the very first time. 31 Mar 2019: The owner continued to find fleas on the dog. 30 Apr 2019, and 30 May 2019: Another vial was applied. The flea issue persisted. Fleas were also noted in the household starting on an unknown date. 3 Jun 2019: The flea issue is still ongoing. The dog has access to a fenced in yard. The dog has not been bathed or gone swimming. There is one other dog and 3 cats in the household that are receiving FRONTLINE and experiencing an issue (see case 19US031936, 19US031937). No further medical information is expected.

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03-Jun-2019	UAE; 19US031195; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 2.50 Year(s) **Weight:** 120 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-May-2019*	02-Jun-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the owner reported the following event for an unknown 2.5 year old, canine, weighing 120 pounds, all other signalment unknown. 20 May 2019: One vial of the FRONTLINE PLUS DOG 89-132 LBS (M64808AR) was applied topically in between the shoulder blades by the owner. 2 Jun 2019: The owner noticed ticks on the pet large and engorged. The pet is indoor mostly and goes outside for potty breaks. The pet has access to an open yard of 5 acres were no wildlife is seen. This is the first time the owner has ticks on the pet. The owner has used FRONTLINE since 2016* on a year round basis. There is another pet in the home having issues with ticks see additional case 19US030953. No further medical information is expected.
02-Jun-2019	UAE; 19US031209; NE; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 5.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG; Unknown antibiotic; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	N/A	25-Apr-2019	N/A	D-D	Suspected Adverse Event: On 2 Jun 2019, the following event was reported to Safety Call International (SCI) by the owner for Rebecca, a 5 pound , 12 year old, female spayed, Yorkshire Terrier . Unknown dates: Rebecca began receiving one chew of HEARTGARD PLUS (68 MCG/57 MG) (B32667, Nov 2021), PO, and unknown FRONTLINE (lot unknown) (product unsubstantiated), applied topically in an unknown location. Both products have since been given monthly on unknown dates without issues. 11 Apr 2019: One chew of HEARTGARD PLUS (68 MCG/57 MG)(B32667 and 30 Nov 2021) was given orally by the pet owner. 12 Apr 2019: The canine presented to the veterinarian for an unknown reason where she also received an unknown dose of an unknown antibiotic. 25 Apr 2019: The patient experienced one episode of emesis and developed soft stool. May 2019 (unknown date): One dose of unknown FRONTLINE was applied topically in a unknown location by the owner. 1 Jun 2019: Rebecca developed mucous in her stool. Presently, the patient has not presented to the veterinarian and it's unknown if any treatment has been given. Her current status is also unknown. She does have a history of experiencing intermittent mucousy/soft stools. No further information is expected.
03-Jun-2019	UAE; 19US031213; MO; U.S.A	**Species:** Feline **Breed:** Chartreux **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 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	17-May-2019	27-May-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the owner reported the following event for Mischa, 8 year old, 15 pound, neutered male, Chartreux feline. 1 May 2019*: The owner purchased a 3 pack of FRONTLINE PLUS CAT (S41108AW). 17 May 2019: One vial was applied between the shoulder blades for the very first time. 27 May 2019: The owner found a deer tick attached, alive, and engorged. The owner removed the tick. There is a dog in the household that received NEXGARD and is experiencing no issue. No further medical information is expected.
03-Jun-2019	UAE; 19US031214; TX; U.S.A	**Species:** Canine **Breed:** Great Pyrenees **Sex:** M **Sex qualifier:** -	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	19-May-2017*	20-May-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 June 2019, the owner reported the following event for Duke, 6 years old, 85 pounds, Intact male, Great Pyrenees. 2017: The dog started on the FRONTLINE on a monthly basis year round. The dog was previously heartworm positive and has gone

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		Age: 6.00 Year(s) **Weight:** 85 lbs				**Other products used:** Unknown Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					through treatment for that. 19 May 2019: The most recent vial of FRONTLINE PLUS DOG 45-88 LBS (J60701AR) was applied between the shoulder blades, by the pet owner. 20 May 2019*: The dog had a moderate amount of fleas. The dog get bathed on a weekly basis with an unknown shampoo. The dog does not have any skin issues. The owner is not seeing any flea activity in the home. The pet owner has treated the fenced in yard. No further medical information is expected.
31-May-2019	UAE; 19US031262; CA; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 30.000 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	15-May-2019*	27-May-2019*	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the pet owner reported the following event for a 30 pound, mixed breed canine of further unknown signalment. Unknown dates: The canine began receiving one vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) applied topically between the shoulder blades. A vial has since been applied monthly, year round. Additionally, the canine is bathed monthly on an unknown date with unknown shampoo. 2017*: The reporter and canine moved to a different area of California, closer to the beach. 15 Mar 2019* - 15 May 2019*: It's been atypically rainy. May 2019* (unknown date): The reporter observed a couple of fleas and lots of flea dirt on the canine. Presently, the issue is ongoing, but it's unclear if any treatment has been administered. No further information is known about the canine's environment including whether or not it goes outside because it was refused by the reporter. There is a second dog in the home who is also receiving FRONTLINE PLUS. A case was also reported for that dog. Please see 19US030708. No further medical information expected.
04-Jun-2019	UAE; 19US031265; -; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 27 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 136MCG/326MG ; **Route:** PO-Oral **Was the product used ok?:** Yes	03-Jun-2019	03-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 04 Jun 2019 an animal owner reported the following event in Rocky, a 10 year old, 27 pound, male neutered, miniature Australian Shepherd. 01 Apr 2019*, 01 May 2019*, 03 Jun 2019: The pet owner applied 1 vial of FRONTLINE PLUS 23-44 LB (lot unknown) and administered 1 chew of HEARTGARD PLUS (136 MCG/114 MG) (lot, expiration unknown) on each listed date. Two hours following product administration, the dog went forward on his front legs as if he was bowing and stretched on his back two legs. He also licked his legs. The dog did not present to the veterinary clinic for examination for any of the events, but the clinical signs resolved within 2 days. The canine has been receiving FRONTLINE PLUS monthly since a puppy without issues. No further information provided nor expected.
04-Jun-2019	UAE; 19US031284; -; U.S.A	**Species:** Canine **Breed:** Coonhound (Black And Tan) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/P	05-May-2019*	05-May-2019*	N/A	D-D	Suspected Adverse Event: On 04 Jun 2019, Animal owner reported the following event for Carly, a 8 year old, 56 pound, spayed female coohhound mix. 01 May 2018: Started HEARTGARD PLUS(272MCG/227MG)(Lot: 8BC0361, May 2021) and applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (Lot: S62202AX) topically between the shoulder blades. *05 May 2019: The most recent chew was administered and 1 vial

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		Weight: 56 lbs				YRANTEL PAMOATE CHEWABLE 272MCG/652MG ; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					was applied to treat a pre-existing flea issue. *05 May 2019: The dog started shedding abnormally and had dandruff and was itching. The pet owner did not see any fleas. 01 Jun 2019: A chew was administered and 1 vial was applied. The dogs symptoms were still ongoing. 02 Jun 2019: The dog became lethargic and started coughing that evening. The dogs nose was dripping. 04 Jun 2019: The dogs symptoms were still ongoing. There are no other dogs in the home. The dog has not been seen by a vet. No further information expected. UPDATE: Per pet owner: On 05 Jun 2019, the shedding is improving. No further information expected.
04-Jun-2019	UAE; 19US031303; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **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)	04-Jun-2019	04-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 4 Jun 2019, a pet owner reported the following event for a 93 pound canine of unknown signalment. 4 Jun 2019: The dog received 0.5 dose of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) topically between the shoulder blades and gagged twice. The dog has not received any treatment and it is unknown if the dog recovered. No further medical information expected.
04-Jun-2019	UAE; 19US031304; -; U.S.A	**Species:** Canine **Breed:** Pomeranian **Sex:** U **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 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	31-May-2019*	04-Jun-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: on 4 Jun 2019, the pet owner reported the following event for a 13 year old, 5 pound*, Pomeranian of further unknown signalment. 1 May 2019* - 22 May 2019*: The reporter temporarily took care of a dog who had fleas and is no longer in the home; however, the reporter did not realize at the time of taking care of said canine that it had fleas. Unknown date: The reporter noticed fleas on her Pomeranian and that the canine was pruritic. 31 May 2019: She applied one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) topically between the shoulder blades. It's unknown if the canine has previously received this product. 4 Jun 2019: The reporter continues to see her dog scratching due to the presence of fleas, but it's unknown if any treatment has been pursued. The reporter is not finding fleas on her or in her home other than what she is finding on the canine. The dog is strictly indoors and does not go outside for bathroom breaks as it is trained to use puppy pads in the house. There are two other dogs in the household. There is a second Pomeranian that also received FRONTLINE PLUS DOG 5-22 LBS and experienced the same issue as reported in this case. Please see 19US031336. The third dog is a 60 pound* Labrador Retriever that lives strictly outside and has no interaction with the two Pomeranians. Additionally, the Labrador Retriever is not being treated with any flea control at this time. No further medical information expected.
04-Jun-2019	UAE; 19US031312; PA; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred)	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products**	01-May-2019*	06-May-2019*	5 Day(s)	D-C	Suspected Adverse Event: On 4 Jun 2019 the pet owner reported the following event for Socketome, a 14 year old (born *1 Jan 2005), spayed female Domestic Mediumhair feline. 1 May 2019*: The pet owner applied FRONTLINE ORIGINAL FOR

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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
		Sex: F **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 12 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					CATS (lot and expiration unknown)(foreign label),1 dose,, topically, intrascapular for the first time. 6 May 2019*: The feline began exhibiting alopecia at the application site. 1 Jun 2019: The pet owner applied a second dose. 3 Jun 2019: The alopecia has worsened to approximately 1 inch in diameter. Currently, the feline has not received treatment and the reaction continues. No further medical information is expected.
04-Jun-2019	UAE; 19US031328; FL; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 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	01-Jun-2019	04-Jun-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Jun 2019, a pet owner reported the following event for Benji, a 3 year old, 75 pound, male neutered German Shepherd. 1 May 2019 and 1 Jun 2019: The owner applied 1 dose of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) topically between the shoulder blades. The owner reported both times the dog had fleas prior to application and after application. 4 Jun 2019: The dog still had fleas and is covered in fleas. The dog is biting, losing hair and has scabs and bleeding. It is unknown if the product is used seasonally or year round. It is unknown if the dog goes outside, to a dog park or the status of the general environment. There is a cat in the house that is not having the same issue. No further medical information expected.
04-Jun-2019	UAE; 19US031336; -; U.S.A	**Species:** Canine **Breed:** Pomeranian **Sex:** U **Sex qualifier:** Unknown **Age:** 12.00 Month(s) **Weight:** 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	31-May-2019	04-Jun-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: on 4 Jun 2019, the pet owner reported the following event for an 12 month old*, 5 pound*, Pomeranian of further unknown signalment. 1 May 2019* - 22 May 2019*: The reporter temporarily took care of a dog who had fleas and is no longer in the home; however, the reporter did not realize at the time of taking care of said canine that it had fleas. Unknown date: The reporter noticed fleas on her Pomeranian and that the canine was pruritic. 31 May 2019: She applied one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) topically between the shoulder blades. It's unknown if the canine has previously received this product. 4 Jun 2019: The reporter continues to see her dog scratching due to the presence of fleas, but it's unknown if any treatment has been pursued. The reporter is not finding fleas on her or in her home other than what she is finding on the canine. The dog is strictly indoors and does not go outside for bathroom breaks as it is trained to use puppy pads in the house. There are two other dogs in the household. There is a second Pomeranian that also received FRONTLINE PLUS DOG 5-22 LBS and experienced the same issue as reported in this case. Please see 19US031304. The third dog is a 60 pound* Labrador Retriever that lives strictly outside and has no interaction with the two Pomeranians. Additionally, the Labrador Retriever is not being treated with any flea control product. No further medical information expected.
04-Jun-2019	UAE; 19US031427; TX; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** F **Sex qualifier:** - **Age:** 7.00 Year(s) **Weight:** 30 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn dish	23-May-2019	26-May-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Jun 2019, the pet owner reported the following event for Lola, a female intact, non-pregnant non-lactating, 30 pound, 7 year old, Australian Shepherd. 23 May 2019: The pet owner bathed the dogs with Dawn dish soap. The pet owner applied one dose of FRONTLINE PLUS DOG 23-44 LBS (S61009AL) topically to skin between the shoulder blades of Lola for the first time.

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						soap; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					26 May 2019: The pet owner first noticed 15+ fleas on both of the dog. 4 Jun 2019: The dog was in good health at time of application. The dog was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen any fleas in the home. The dog has no history of skin problems or any other issues with topical treatments. The dog has not had flea problem before in the past. The dogs has not received any other medications or topical treatments. The dog has not been bathed. The dog is indoors and outside for walks. The current status of the dog is unknown. Lola shares home with one other dog treated with FRONTLINE PLUS DOG 5-22 LBS (S62502AW) with case number 19US035093. No further medical information.
04-Jun-2019	UAE; 19US031433; NJ; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** - **Age:** 11.00 Week(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?:** Unknown to Company	28-May-2019*	04-Jun-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: 04 Jun 2019: A office manager reported the following event in Luna; an 11 week old, 10.5 pounds, intact, female, Labrador Retriever. 28 May 2019*: The breeder administered one vial of FRONTLINE PLUS DOGS 5-22 LBS (lot unknown, package unavailable) on the shoulders. It is unknown if fleas were seen, bathing, environment, or exposure conditions. 04 Jun 2019: The owner is seeing fleas. There is a cat in the home being treated with FRONTLINE PLUS CATS (lot unknown, package unavailable) (case 19US031507). No further information expected.
30-May-2019	UAE; 19US031445; IL; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **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	05-May-2019	05-May-2019	0 Day(s)	D-C	Suspected Adverse Event: On 30 May 2019, the pet owner reported th following event for a large crossbred (>20kg), all signalments unknown. 5 May 2019: 1 vial of FRONTLINE PLUS DOG 45-88 LBS(lot and expiration unknown) was applied to the dog in one area between the shoulder blade. The dog was unable to stand after the application. The owner gave an unknown pain medication leftover from a previous unrelated event. 6 May 2019: The dog recovered. The dog was not seen by the veterinerian. There is one other dog in the home that experienced symptoms following the use of FRONTLINE PLUS, see case 19US030111. The dog has been on FRONTLINE montly since 2012. No further medical information is expected.
04-Jun-2019	UAE; 19US031456; CA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 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 / Cutaneous **Was the product used ok?:** Yes	01-May-2019*	25-May-2019	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Jun 2019, the owner reported the following event for Ember, a 10 year old, 11 pound, neutered male Domestic Longhair. 1 May 2019*, 1 Jun 2019*: The cat received doses of FRONTLINE PLUS FOR CATS (S40815AW), applied topically between the shoulder blades by the animal owner. 25 May 2019: The owner observed over 10 fleas on the cat. The owner continues to find fleas on the cat although there are no fleas in the home. The cat goes outside and is bathed occasionally but was not bathed after FRONTLINE administration. Per the owner, no fleas were seen on the cat prior to FRONTLINE adminstration. It is unknown if the product is used on a seasonal basis or year-round. No further medical information expected.

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04-Jun-2019	UAE; 19US031468; -; U.S.A	**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	01-Jan-2018*	04-Jun-2019*	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Jun 2019, the owner reported the following event for 10 felines with unknown signalment. 2018*: The cats started on yearly on FRONTLINE PLUS CATS (Lot Unknown). May 2019*: The owner saw fleas on an unknown number of indoor and outdoor cats. 1 Jun 2019*: The most recent dose was applied. 4 Jun 2019*: The owner stated that he is still seeing fleas. The owner did report that 6 are indoor cats and 4 are outdoor cats. The owner states that their only interaction with one another is through the screened in porch. The purchase history is unknown. No further information at this time.
04-Jun-2019	UAE; 19US031469; VA; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 60 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN CHEWABLE 136 MCG; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-May-2018*	28-May-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Jun 2019, the pet owner reported the following event for Nero a male neutered, 60 pound, 5 year old, Retriever (Labrador, Black). Unknown dates: Nero is administered HEARTGARD CHEWABLE (lot number unknown, expiration unknown) (Product unsubstantiated). 14 May 2019: Nero was presented to veterinarian for routine exam but was not treated. 21 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (S60809AX) topically to skin between the shoulder blades of Nero monthly on year round basis. 28 May 2019: The pet owner noticed 15+fleas on the body of Nero. 31 May 2019: The pet owner bathed Nero with Burt's Bees oatmeal shampoo. Nero was in good health at time of application. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. Nero has no history of skin problems or any other issues with topical treatments. Nero has had flea problem before in the past and it resolved. Nero has not received any other medications or topical treatments. Nero is indoors and outside for walks 3x a day. The current status of Nero is unknown. Nero shares home with one dog that is treated with FRONTLINE PLUS with no issues. No further medical information.
04-Jun-2019	UAE; 19US031491; CA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 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	31-May-2019	31-May-2019	0 Day(s)	D-D	Suspected Adverse Event: On the 4 Jun 2019, a pet owner reported the following event for Hido, a 10 pound, 4 year old, neutered male, Domestic Shorthair. 31 May 2019: The pet owner applied for the first time, 1 dose of FRONTLINE PLUS CATS (R40801AW) topically between the shoulder blades. A few hours later the cat began scratching and chewing the fir on his back. The cat does not let the pet owner inspect the area so she is unaware if the skin is red. The cat has not seen his veterinarian or received any treatment. The issue is ongoing. No further medical information expected.
04-Jun-2019	UAE; 19US031507; NJ; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products**	28-May-2019*	04-Jun-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: 04 Jun 2019: A office manager reported the following event in a cat of unknown signalment, never seen in the clinic. 28 May 2019*: The owner administered one vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) on the shoulders. 04 Jun 2019: The owner is seeing fleas. There is a dog in the home being treated with FRONTLINE PLUS DOGS (lot unknown,

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		Age: - **Weight:** Unknown				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					package unavailable) (case 19US031433). No further information expected.
04-Jun-2019	UAE; 19US031512; WA; U.S.A	**Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** M **Sex qualifier:** - **Age:** 12.00 Year(s) **Weight:** 20 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown flea shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-May-2019*	21-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 June 2019, the owner reported the following event for Rusty, a 12 year old, 20 pound, intact male Pinscher (miniature). *21 May 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S61017AL) was topically applied to the skin between the shoulder blades. *22 May 2019: Rusty continued to have fleas. Prior to the application the owner noticed fleas in the home, but is noticing a decrease since the application. The dog has a large number of fleas and goes outside daily for potty breaks in a grass yard. The dog is bathe once a month with flea shampoo. Rusty has been on FL seasonally for the past 5 years. No further information available.
04-Jun-2019	UAE; 19US031519; CA; U.S.A	**Species:** Canine **Breed:** Boxer **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Month(s) **Weight:** 30 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	03-Jun-2019	03-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Jun 2019, the pet owner reported the following event for Honey a female spayed, 30 pound, 5 months old, Boxer / Medium crossbreed. 3 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 23-44 LBS (S61009AL) topically to skin between the shoulder blades of Honey for the first time. The pet owner noticed 5-15* fleas on the body of Honey 6 hours post application. The pet owner bathed the dog with Dawn dish soap. 4 Jun 2019: Honey was in good health at time of application. Honey was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. Honey has no history of skin problems or any other issues with topical treatments. Honey has not had flea problem before in the past. Honey has not received any other medications or topical treatments. Honey is indoors and outside for walks. The current status of Honey is unknown. No further medical information.
04-Jun-2019	UAE; 19US031537; -; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 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	N/A	20-May-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Jun 2019, the pet owner reported the following event for Isabella, a 2 year old, 5 pound, spayed female, Yorkshire Terrier. Unknown date: The canine began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (S60302AL) applied topically between the shoulder blades. A vial has since been applied monthly on the eleventh, year round, though the purchase history is unknown. 11 May 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS was applied as previously described. 20 May 2019*: The reporter began seeing an unknown number of fleas on Isabella. Presently, she's not finding fleas in the home, but just on the dog and it's unknown if any treatment has been given for the ongoing issue. There is a second dog in the home who also receives the product and is picking up fleas. Please see case 19US031544. No further medical information expected.

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04-Jun-2019	UAE; 19US031544; -; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** - **Age:** 5.00 Year(s) **Weight:** 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	11-May-2019	20-May-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Jun 2019, the pet owner reported the following event for Bleu, a 5 year old, 5 pound, intact male, Yorkshire Terrier. Unknown date: The canine began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (S60302AL) applied topically between the shoulder blades. A vial has since been applied monthly on the eleventh, year round, though the purchase history is unknown. 11 May 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS was applied as previously described. 20 May 2019*: The reporter began seeing an unknown number of fleas on Bleu. Presently, she's not finding fleas in the home, but just on the dog and it's unknown if any treatment has been given for the ongoing issue. No information regarding the patient's environment including whether or not he goes outside could be confirmed. There is a second dog in the home who also receives the product and is picking up fleas. Please see case 19US031537. No further medical information expected.
04-Jun-2019	UAE; 19US031578; -; U.S.A	**Species:** Canine **Breed:** Spaniel (Brittany) **Sex:** U **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:** Topical / Cutaneous **Was the product used ok?:** Yes	25-May-2019	04-Jun-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Jun 2019, the owner reported the following event for a 50 pound, Brittany Spaniel canine (all other signalments unknown). 25 May 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (P61401AR) was applied between the shoulder blades for the very first time. 4 Jun 2019: The owner found 2 deer ticks attached to the pet. The owner removed the ticks and they were still alive. The dog has access to open country. There is one other dog in the household that received the product and is expericing an issue (see case 19US031580). No further medical information is expected.
04-Jun-2019	UAE; 19US031580; -; U.S.A	**Species:** Canine **Breed:** Wheaton Terrier **Sex:** U **Sex qualifier:** Unknown **Age:** - **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	25-May-2019	04-Jun-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Jun 2019, the owner reported the following event for a 34 pound, Weaton Terrier canine. 25 May 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (M61010BL) was applied between the shoulder blades for the very first time. 4 Jun 2019: The owner found 2 deer ticks walking through the pets fur. The owner removed the ticks. The dog has access to open country. There is one other dog in the household that received the product and is expericing an issue (see case 19US031578). No further medical information is expected.
04-Jun-2019	UAE; 19US031591; 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	26-May-2019*	04-Jun-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 June 2019, the owner reported the following event for a feline (all other signalments unknown). 26 May 2019: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades, by the pet owner. 4 June 2019: The cat had 1 tick. No further medical information is expected.

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						Was the product used ok?: Yes					
05-Jun-2019	UAE; 19US031625; -; U.S.A	**Species:** Canine **Breed:** Dachshund **Sex:** F **Sex qualifier:** Neutered **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?:** Unknown to Company	03-Jun-2019	05-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 05 Jun 2019, Animal owner reported the following event for Ellie, a 24 pound, spayed female, dachshund mix. Jun 2019: The pet owner noticed several fleas on the dog 03 Jun 2019: The pet owner applied the contents of 1 vial of FRONTLINE PLUS DOG 23-44 LBS (Lot unknown) topically to an unknown location fir the first time. The pet owner spilt some of the product on her hands during the application process (case reported in 19US031630). 05 Jun 2019: The pet owner reported the dog is lethargic and has been since applying the product. The dog broke its toenail a few days ago and has not wanted to walk but the owner thinks the product is making her dog lethargic. No treatments have been given. There is 1 cat in the home but unknown if the cat is on flea prevention. The pet owner has flea bites on her ankles and feet. It is unknown if the environment has been treated. No further information expected.
05-Jun-2019	UAE; 19US031646; OH; U.S.A	**Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** X **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 5 - 11 lbs	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Adams flea and tick shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Nov-2018*	30-May-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 5 Jun 2019, the pet owner reported the following event for 4 cats, 3 females spayed, 1 male neutered, 2-13 years old, 5-11 pounds, Feline mixed/various breeds. 28 May 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S40410AW) topically to skin between the shoulder blades to the cats on monthly basis. 30 May 2019: The pet owner noticed 1-5 fleas on the body of the cats. 2 Jun 2019: The pet owner bathed one cat with Adams flea and tick shampoo. 5 Jun 2019: The cats were in good health at time of application. The cats were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. The cats have no history of skin problems or any other issues with topical treatments. The cats have not had flea problem before in the past. The cats have not received any other medications or topical treatments. The cats are strictly indoors. The current status of the cats are unknown. No further medical information.
22-May-2019	UAE; 19US031651; -; U.S.A	**Species:** Canine **Breed:** Pug **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 29 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 136MCG/326MG ; **Route:** Topical /	01-Apr-2019*	01-Apr-2019*	0 Day(s)	D-C	Suspected Adverse Event: On 22 May 2019, a pet owner reported the following event for Baxter, a 9 year old, 29 pound, male neutered Pug x Beagle. 2011*: Dog started receiving HEARTGARD PLUS (136 mcg/114 mg) (Lot and exp unknown) and FRONTLINE PLUS DOG 23-44 LBS (lot unknown) monthly. UNKNOWN DATE: The patient began acting lethargic, severely aggressive, having chronic diarrhea, not wanting to drink, excessively flatulence, coughing, and sneezing. The owner was unable to provide a time frame for these symptoms. It is unknown if the dog presented to a clinic or received treatment, but at the time of making the report the symptoms had resolved. There are no further details available. The owner also reported another case with FRONTLINE PLUS at the same time: see case 19US28659. No further medical information 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
						Cutaneous **Was the product used ok?:** Yes					UPDATE 19 Jun 2019: Corrected EN intro statement.
03-Jun-2019	UAE; 19US031658; NC; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **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	01-Jun-2019	01-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, a pet owner reported the following event for Princess, an approximately 8 year old, 100 pound, spayed female Pit Bull mix. 1 Jun 2019: The dog received 1 application of FRONTLINE PLUS DOG 89-132 LBS (S62006AX) topically between the shoulder blades for the first time because the dog had fleas. Later on that day the dog was scratching and the pet owner noticed a moderate amount of fleas on the dog. The pet owner has continued to see fleas on the dog daily and the dog has continued to scratch. The pet owner is not getting bit but is seeing some live fleas on the bed. The yard is not fenced in and there are woods behind the house that the dog has access to. The pet owner stated that he has used FRONTLINE in the past on other dogs and has never had an issue with fleas. There is 1 other dog in the home that is on FRONTLINE and has fleas, see case 19US031122. No further medical information expected.
05-Jun-2019	UAE; 19US031659; GA; U.S.A	**Species:** Canine **Breed:** Staffordshire Terrier **Sex:** M **Sex qualifier:** - **Age:** 4.00 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	16-May-2019	05-Jun-2019	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 5 Jun 2019, the pet owner reported the following event for Optimus, a 4 year old, 80 pound, intact male Staffordshire terrier. 1 Jan 2019: The dog began receiving monthly doses of FRONTLINE PLUS DOG 45-88 LBS (S62111AL) 16 May 2019: The most recent dose was applied. 5 Jun 2019: The pet owner reported seeing more than 20 fleas on the dog. The dog does go outside on leashed walks and no fleas have been seen in the house at this time. No further medical information expected.
05-Jun-2019	UAE; 19US031666; 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:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Mar-2019	03-Mar-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 05 Jun 2019, the animal owner reported the following event for four felines of unknown signalment. 02 Mar 2019, 02 Apr 2019, 02 May 2019, and 02 Jun 2019: They received FRONTLINE PLUS CATS (R41201AW) one dose topically per animal in between the shoulders. 03 Mar 2019: The owner noticed a moderate amount of fleas. The cats are indoor only. The owner noticed fleas on all of the pets prior to application. The owner is not seeing fleas off of the pets. They have not presented to veterinary clinic. The owner has been treating by bathing all of the animals in the household in Dawn dish soap every two weeks. There is one canine in the household receiving FRONTLINE PLUS DOG 23-44 LBS (see case 19US031675) and two canines in the household receiving FRONTLINE PLUS DOG 89-132 LBS (see case 19US031677). No further medical information expected.
05-Jun-2019	UAE; 19US031675; OH; U.S.A	**Species:** Canine **Breed:** Bichon Frise **Sex:** U **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	02-Mar-2019	03-Mar-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 05 Jun 2019, the animal owner reported the following event for one canine, unknown age, 23.0 pound, unknown sex, unknown reproductive status, Bichon Frise Mix. 02 Mar 2019, 02 Apr 2019, 02 May 2019, and 02 Jun 2019: The

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		Unknown **Age:** - **Weight:** 23.0 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					canine received FRONTLINE PLUS DOG 23-44 LBS (H65002AL) one dose topically per animal in between the shoulders. 03 Mar 2019: The owner noticed a moderate amount of fleas. The dog frequent the yard which has tall grass. The owner noticed fleas on all of the pets prior to application. The owner is not seeing fleas off of the pets. They have not presented to veterinary clinic. The owner has been treating by bathing all of the animals in the household in Dawn dish soap every two weeks. There are four felines in the household receiving FRONTLINE PLUS CAT (see case 19US031666) and two canines in the household receiving FRONTLINE PLUS DOG 89-132 LBS (see case 19US031677). No further medical information expected.
05-Jun-2019	UAE; 19US031677; OH; U.S.A	**Species:** Canine **Breed:** St. Bernard **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 120.0 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn soap; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Mar-2019	03-Mar-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 05 Jun 2019, the animal owner reported the following event for two canines, 12 years old*, 120.0 pounds*, unknown sex, unknown reproductive status, St. Bernards. 02 Mar 2019, 02 Apr 2019, 02 May 2019, and 02 Jun 2019: They received FRONTLINE PLUS DOG 89-132 LBS (R61814AR) and (J63501AR) one dose topically per animal in between the shoulders. 03 Mar 2019: The owner noticed a moderate amount of fleas. The dogs frequent the yard which has tall grass. The owner noticed fleas on all of the pets prior to application. The owner is not seeing fleas off of the pets. They have not presented to veterinary clinic. The owner has been treating by bathing all of the animals in the household in Dawn dish soap every two weeks. There are four felines in the household receiving FRONTLINE PLUS CAT (see case 19US031666) and one canine in the household receiving FRONTLINE PLUS DOG 23-44 LBS (see case 19US031675). No further medical information expected.
05-Jun-2019	UAE; 19US031699; CA; U.S.A	**Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 5 - 6 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-May-2018	15-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 5 Jun 2019, the pet owner reported the following event for 2 cats, females spayed, 5-6 pounds, 2 years old, Feline mixed/ various breeds. 15 May 2019: The pet owner first noticed 15+ fleas on the cats. The pet owner applied one dose of FRONTLINE PLUS CATS (S40502AX) topically to skin between the shoulder blades of the cats on monthly basis year round. 16 May 2019: The pet owner continued to see 15+ fleas on the cats. 5 Jun 2019: The cats were in good health at time of application. The cats were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has seen fleas in the home jumping and biting his spouse. The cats have no history of skin problems or any other issues with topical treatments. The cats have not had flea problem before in the past. The cats have not received any other medications or topical treatments. The cats have not been bathed. The cats are indoors and outside. The current status of the cats are unknown. No further medical information.
05-Jun-2019	UAE; 19US031725; OH; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	02-Jun-2019	02-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 5 Jun 2019, the pet owner reported the following event for Jojo a male neutered, 80 pound, 9 year old, Large Crossbreed. Unknown dates: The pet owner has used FRONTLINE PLUS DOG 45-88 LBS in the past. 2 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (lot number unknown) topically to skin

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		Age: 9.00 Year(s) **Weight:** 80 lbs				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					between the shoulder blades of Jojo for the first time this year. After unknown duration of time post application the pet owner noticed Jojo experience lethargy not wanting to eat. 5 Jun 2019: Jojo was in good health at time of application. Jojo was not presented to veterinarian. Jojo has not had any other products at the same time as the FRONTLINE PLUS DOG 45-88 LBS application. Jojo does not have history of drug or vaccine reactions. Jojo has not had FRONTLINE prior to reaction. Jojo is currently at home with ongoing issue. No further medical information.
05-Jun-2019	UAE; 19US031748; OH; U.S.A	**Species:** Canine **Breed:** Schnauzer **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 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	01-May-2019	01-May-2019	N/A	D-D	Suspected Adverse Event: On 5 June 2019, the owner reported the following event for Sara, 3 years old, 18 pounds, spayed female, Schnauzer/ Yorkshire Terrier crossbreed. 1 May 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades, by the pet owner. 6 hours later the dog started to extremely itch. No fleas were seen on the dog. 1 June 2019: The itching continued and the most recent vial of FRONTLINE PLUS was applied. The dog did not present to clinic and no treatment was provided. 5 June 2019: The dog is still itching. The dog received the FRONTLINE previously on a few unknown dates about 3 years ago with no reactions noted. There are 2 other dogs in the home using FRONTLINE PLUS as well with cases 19US031759 and 19US031766. No further medical information is expected. UPDATE 5 Jun 2019: Per the owner, lot number is S60401AX. No further medical information is expected.
05-Jun-2019	UAE; 19US031759; OH; U.S.A	**Species:** Canine **Breed:** Schnauzer **Sex:** F **Sex qualifier:** Neutered **Age:** 15.00 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	01-May-2019	01-May-2019	N/A	D-D	Suspected Adverse Event: On 5 June 2019, the owner reported the following event for Paris, 15 years old, 26 pounds, spayed female, Schnauzer. 1 May 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades, by the pet owner. 6 hours later the dog started to extremely itch. No fleas were seen on the dog. 1 June 2019: The itching continued and the most recent vial of FRONTLINE PLUS was applied .The dog did not present to clinic and no treatment was provided. 5 June 2019: The dog is still itching. The dog received the FRONTLINE previously on a few unknown dates about 3 years ago with no reactions noted. There are 2 other dogs in the home using FRONTLINE PLUS as well with cases 19US031748 and 19US031766. No further medical information is expected. UPDATE 5 Jun 2019: Per the owner, lot number is S62308AW. No further medical information is expected.
05-Jun-2019	UAE; 19US031766; OH; U.S.A	**Species:** Canine **Breed:** St. Bernard **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 150 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	01-May-2019	01-May-2019	N/A	D-D	Suspected Adverse Event: On 5 June 2019, the owner reported the following event for Rosie, 5 years old, 150 pounds, spayed female,St. Bernard. 1 May 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) was applied between the shoulder blades, by the pet owner. 6 hours later the dog started to extremely itch. No fleas were seen on the dog. 1 June 2019: The itching continued and the most recent vial of FRONTLINE PLUS was applied. The dog did not present to clinic and no treatment was provided.

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						Was the product used ok?: No (Low dose)					5 June 2019: The dog is still itching. The dog received the FRONTLINE previously on a few unknown dates about 3 years ago with no reactions noted. There are 2 other dogs in the home using FRONTLINE PLUS as well with cases 19US031759 and 19US031748. No further medical information is expected. UPDATE 5 Jun 2019: Per the owner, lot number is P61704AR. No further medical information is expected.
05-Jun-2019	UAE; 19US031784; CA; U.S.A	**Species:** Canine **Breed:** Welsh Corgi (Pembroke) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(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 (Low dose)	01-May-2019	06-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 5 Jun 2019, the pet owner reported the following event for Gracie, a 6 year old, 23 pound, spayed female, Pembroke Welsh Corgi. 1 Apr 2019*: The owner was seeing a few fleas on the animal. 1 May 2019: She began receiving FRONTLINE PLUS 5-22 LBS(S60810AX). 6 May 2019*: The owner noticed fleas. 1 Jun 2019: She received her monthly FRONTLINE PLUS 5-22 LBS(S60810AX). 2 Jun 2019*: The owner noticed she is still seeing fleas. The dog does frequent outside for potty breaks and play. Mild infestation on animal states owner, and she is not seeing them in the house. The animal is bathed roughly twice monthly with Dawn dish soap. Her current condition is ongoing. There a total of 1 canines in the household. She was on FRONTLINE PLUS 23-44 LBS prior to the last two doses, but exact start date is unknown but owner stated she had used FRONTLINE for years and was using FRONTLINE PLUS 23-44 LBS prior to FRONTLINE PLUS 5-22 LBS. She has also had a reaction to Advantage Multi, were she became slightly ill and had to stop use. No further medical information expected.
03-Jun-2019	UAE; 19US031788; KY; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Neutered **Age:** - **Weight:** 5 - 23 lbs*	8	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Cat Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	26-May-2019	03-Jun-2019	8 Day(s)	D-D	Suspected Adverse Event: On 3 Jun 2019 the pet owner reported the following event via email for four unknown 5-23 pound, neutered, felines. All other signalments are unknown. *19 May 2019: The owner bathed the cats with an unknown cat shampoo. 26 May 2019: The owner applied 1 vial of African labeled FRONTLINE PLUS CATS (S40705B) to the skin between the shoulder blades for the very first time. 3 Jun 2019: The owner noticed a wound on each of the cats at the application site that resembled a chemical burn and ranged in size from 1cm to 1in on each of the cats. The cats did not present to the vet clinic. The symptoms are ongoing. There are a total of 10 cats in the household and 1 dog that all received the same product. 2 of the cats exhibited symptoms as well with case number 19US030969 and 19US030991. The remaining 8 cats and 1 dog were still showing fleas with case number 19US30994 and 19US31019. No further medical information expected.
05-Jun-2019	UAE; 19US031840; NC; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **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 /	04-Jun-2019	05-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 5 Jun 2019, the owner reported the following event for Charlie, 10 year old, 10 pound, neutered male, Domestic Shorthair feline. 4 Jun 2019: One vial of FRONTLINE PLUS CATS (S40717AW) was applied between the shoulder blades. 5 Jun 2019: The cat experiencing alopecia localized at the application site. The pet did not present to the clinic and no treatment was provided. The cat received the product before in 2018* and experienced no

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						Cutaneous **Was the product used ok?:** Yes					issue. No further medical information is expected.
05-Jun-2019	UAE; 19US031853; HI; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 15.00 Year(s) **Weight:** 12.5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Benazepril; Hydrocodone Bitartrate; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	08-Apr-2019	08-Apr-2019	N/A	D-C	Suspected Adverse Event: On 5 Jun 2019 the clinic staff reported the following event for Thumper a 15 year old 12.5 pound female spayed Chihuahua and Papillon mix. *Dec 2018: The dog was started on Benazepril and Hydrocodone bitartrate on a daily basis thereafter. 8 Apr 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S61602AX) to the skin between the shoulder blades and halfway down the back for the first time ever. At an unknown point later the dog began scratching a little bit. 11 May 2019: The owner applied another dose in the same manner. *15 May 2019: The dog began pulling her fur out of the application site and the dog began breaking out all over the body mainly on the belly. *27 May 2019: The dog presented to the vet clinic and was treated with Benadryl. The symptoms are ongoing. The dog has a history of a heart murmur and flea allergy dermatitis. Owner has not seen any fleas on the dog. No further medical information expected.
05-Jun-2019	UAE; 19US031861; MI; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 8 - 10 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	23-Apr-2019	20-May-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 5 Jun 2019, the pet owner reported the following event for 2 dogs, males neutered, 8-10 pounds, 10-14 years old, Mixed breeds/ various breeds. 23 Apr 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS topically to skin between the shoulder blades of the dogs for first time this year. 20 May 2019: The pet owner first noticed 15+ fleas on the dogs. 23 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) topically to skin between the shoulder blades of the dogs on monthly basis. 24 May 2019: The pet owner continued to see 15+ fleas on the dogs. 28 May 2019: The pet owner bathed the dogs with VetMD flea and tick shampoo. 5 Jun 2019: The dogs were in good health at time of application. The dogs were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has seen fleas in the home jumping and biting her. The dogs have no history of skin problems or any other issues with topical treatments. The dogs have not had flea problem before in the past. The dogs have not received any other medications or topical treatments. The dogs are indoors and outside in fenced yard. The current status of the dogs are unknown. No further medical information.
05-Jun-2019	UAE; 19US031863; MO; U.S.A	**Species:** Feline **Breed:** Siamese **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 8.5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical /	05-May-2019*	05-May-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 5 June 2019, the owner reported the following event for Fettuccine, a one year old, 8.5 pound, neutered male, Siamese. *5 May 2019: One vial of FRONTLINE PLUS CATS (S41201AX) was topically applied to the skin between the shoulder blades for the first time. *Unknown date: The cat started to pickup ticks and continued to pick up 1-3 ticks daily. The cat is indoor and outdoor and is exposed to wooded environments. No further information available.

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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?:** Yes					
05-Jun-2019	UAE; 19US031889; WI; U.S.A	**Species:** Canine **Breed:** Pointer **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 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?:** Unknown to Company	05-Jun-2019	05-Jun-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 5 Jun 2019, the owner reported the following event for Kate, 2 year old, 45 pound, spayed female, Pointer canine. Unknown date: One vial of FRONTLINE PLUS DOG 45-88 LBS (B62104AR) was applied between the shoulder blades. After an unknown amount of time the pet experiencing loose stool. It is unknown if the pet presented to the clinic or if any treatment was provided. The current status of the pet is unknown. No further medical information is expected.
05-Jun-2019	UAE; 19US031893; CA; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 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?:** Yes	28-May-2019	03-Jun-2019	6 Day(s)	D-D	Suspected Adverse Event: On 5 Jun 2019, the owner reported the following event for Boo, a 4 year old, 10 pound, male, neutered, Domestic medium hair. 28 May 2019: One vial of FRONTLINE PLUS CATS (S40210CW) was applied topically in between the pet's shoulder blades by the owner. 3 Jun 2019: The owner noticed skin irritation and itching at the application site. The owner has not presented the pet to the clinic. 5 Jun 2019: The cat's symptoms are still ongoing. The pet has been using FRONTLINE since 2018*.No further medical information expected.
05-Jun-2019	UAE; 19US031932; SD; U.S.A	**Species:** Canine **Breed:** Cairn Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 41 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-May-2019	31-May-2019	0 Day(s)	D-D	Suspected Adverse Event: On 5 Jun 2019, the pet owner reported the following event for Lacey, a 41 pound, 2 year old, female spayed, Carin Terrier Border Collie mix. 31 May 2019: 1 vial of FRONTLINE PLUS DOG 23-44 LBS (S61417AL) was applied to the dog in one area between the shoulder blades for the first time. Right away she seemed to be really itchy and agitated. 2 Jun 2019: She began loosing large amounts hair. The owner bathed her in an unknown pet shampoo. Her hair was matted in certain areas across her body and there was oily residue. The owner tried to brush her and she acted as if it was painful. 4 Jun 2019: She was seen by the veterinarian. A physical exam was done and Apoquel 16 mg was prescribed to be given PO q12 hours. 5 Jun 2019: The hair loss is not as bad and she is not scratching as much, symptoms are ongoing. No further medical information is expected.
03-Jun-2019	UAE; 19US031936; CA; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	30-Mar-2019	03-Jun-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the owner reported the following event for a 3 year old, 10 pound, neutered male, Small Crossbreed canine. Unknown date: The owner started to notice fleas on the dog. 30 Mar 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades for the very first time.

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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
		Age: 3.00 Year(s) **Weight:** 10 lbs				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					31 Mar 2019: The owner continued to find fleas on the dog. 30 Apr 2019, and 30 May 2019: Another vial was applied. The flea issue persisted. Fleas were also noted in the household starting on an unknown date. 3 Jun 2019: The flea issue is still ongoing. The dog has access to a fenced in yard. The dog has not been bathed or gone swimming. There is one other dog and 3 cats in the household that are receiving FRONTLINE and experiencing an issue (see case 19US031189, 19US031937). No further medical information is expected.
03-Jun-2019	UAE; 19US031937; CA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 6 - 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	30-Mar-2019	03-Jun-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jun 2019, the owner reported the following event for a 3 felines, between 6-12 pounds (all other signalments unknown). Unknown date: The owner started to notice fleas on the dog. 30 Mar 2019: One vial of FRONTLINE PLUS CATS (S40502AX) was applied between the shoulder blades for the very first time. 31 Mar 2019: The owner continued to find fleas on the cats. 30 Apr 2019, and 30 May 2019: Another vial was applied. The flea issue persisted. Fleas were also noted in the household starting on an unknown date. 3 Jun 2019: The flea issue is still ongoing. The cats are stictly indoor. The dog has not been bathed or gone swimming. There are 2 other dogs in the household that are receiving FRONTLINE and experiencing an issue (see case 19US031936, 19US031189). No further medical information is expected.
06-Jun-2019	UAE; 19US031944; VA; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 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	21-May-2019	05-Jun-2019	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 6 Jun 2019, the pet owner reported the following event for Benny a male neutered, 10 pound, 10 year old, Maltese. Unknown dates: The pet owner has used unknown amount of FRONTLINE PLUS year before on monthly basis. 21 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S62502AW) topically between the shoulder blades to the body of Benny for the first time. 5 Jun 2019: The pet owner noticed 1-2 fleas on the body of Benny. 6 Jun 2019: Benny was in good health at time of application. Benny was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen any fleas in the home. Benny has no history of skin problems or any other issues with topical treatments. Benny has not had flea problem before in the past. Benny has not received any other medications or topical treatments. Benny has not been bathed. Benny is indoors and outside for walks. The current status of Benny is unknown. No further medical information. UPDATE 21 JUN 2019: The owner reported the following information via phone call. 20 Jun 2019: The owner applied another dose. 21 Jun 2019: The owner continued seeing 1 fleas running around like crazy on the abdomen of the dog. No further medical information expected. UPDATE 1 Jul 2019: Per owner pet is covered in fleas. No further information available at this time. UPDATE 1 Jul 2019: Per the pet owner, she is currently finding fecal matter from the fleas on her dog and is observing fleas jumping off of her dog. No further medical information expected.

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06-Jun-2019	UAE; 19US031946; MI; 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	31-May-2019	31-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 6 June 2019, the owner reported the following event for a 7 pound cat (signalment unknown). 31 May 2019: One vial of FRONTLINE PLUS CATS (S41103AW) was applied to the skin between the shoulder blades. On an unknown date after the treatment the cat was groomed and the groomer found 4 fleas. The cat is treated monthly year round and has never had an issue with fleas in the past. The cat is indoor and outdoor and there aren't any fleas in the home. No further information available.
06-Jun-2019	UAE; 19US031959; -; U.S.A	**Species:** Canine **Breed:** Beagle **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 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 product used ok?:** Yes	05-Jun-2019	05-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 06 Jun 2019 an animal owner reported the following event in Duke, a 4 year old, 30 pound, male neutered, Beagle. 05 Jun 2019: The canine was administered FRONTLINE PLUS 23-44 lb (lot, expiration unknown) between the shoulder blades in the morning. That evening (approximately 8 hours post administration) the canine became lethargic and was not eating. 06 Jun 2019: The canine had continued clinical signs along with shaking legs. No treatments or diagnostics at time of report. Canine has a preexisting history of mild seizures that resolve on own without medication. Canine healthy otherwise. No further information provided nor expected.
06-Jun-2019	UAE; 19US031977; -; 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-Jun-2019*	01-Jun-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 6 Jun 2019, the pet owner reported the following event for an unknown number of felines of further unknown signalment. Unknown dates: The reporter applied FRONTLINE PLUS CATS (lot unknown) topically in unknown locations on the cats and while applying it to them, the cats did not like it. The reporter did not specify what it was that the cats did not like and did not further describe what the cats were doing when she applied the product. It's unknown if the felines have previously received this product and their current statuses are also unknown. No further medical information expected.
06-Jun-2019	UAE; 19US031984; FL; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Hartz Ultraguard Plus; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Jun-2019	06-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On the 6 Jun 2019, a pet owner reported the following event for Bella, a 10 pound, 5 year old, spayed female, Chihuahua Mix. 14 May 2019: The owner applied 1 dose of Hartz Ultraguard Plus, topically between the shoulder blades as a flea and tick control to her dog. She was not seeing any fleas on her dog. 5 Jun 2019: The pet owner applied for the first time 1 dose of FRONTLINE PLUS DOG 5-22 LBS (S62502AW), with 1 dose applied topically between the shoulder blades. Prior to the product being applied the pet owner was seeing fleas on her dog and the dog would scratch once in a while due to the fleas. 6 Jun 2019: The dog started scratching excessively all over the body especially over the base of the tail. The owner noticed that there was some erythema on the abdomen. The dog has not seen her veterinarian for this reaction and has not

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											received any treatment. The symptom is ongoing. The pet owner reported another event for the housemate see case 19US031986. No further medical information expected. UPDATE 12 Jun 2019: Per pet owner, the dog has fleas and is still scratching. The scratching has decreased since immediately after applying the product, but is still present. Caller was not receptive to product education. No further medical information expected.
06-Jun-2019	UAE; 19US031986; FL; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 3.5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Hartz Ultraguard Plus; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	05-Jun-2019	06-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On the 6 Jun 2019, a pet owner reported the following event for Chiquita, a 3.5 pound, 3 year old, spayed female, Long Haired Chihuahua. 14 May 2019: The owner applied 1 dose of Hartz Ultraguard Plus, topically between the shoulder blades as a flea and tick control to her dog. She was not seeing any fleas on her dog at the time. 5 Jun 2019: The pet owner applied for the first time 1 dose of FRONTLINE PLUS DOG 5-22 LBS (S62502AW), with 1 dose applied topically between the shoulder blades. Prior to the product being applied, the pet owner was seeing fleas on her dog and the dog would scratch once in a while due to the fleas. 6 Jun 2019: The dog started scratching excessively all over the body especially over the base of the tail. The owner noticed that there was some erythema on the abdomen. The dog has not seen her veterinarian for this reaction and has not received any treatment. The symptom is ongoing. The pet owner reported another event for the housemate see case 19US031984. The product is not being used per the label as the dog is 3.5 pounds and it is labeled for dogs 5-22 lbs. No further medical information expected. UPDATE 12 Jun 2019: Per pet owner, the dog has fleas and is still scratching. The scratching has decreased since immediately after applying the product, but is still present. Caller was not receptive to product education. No further medical information expected.
06-Jun-2019	UAE; 19US032063; CT; U.S.A	**Species:** Canine **Breed:** Australian Cattle Dog **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 38.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** RECOMBITEK LYME - 2126.R0; Zoetis Lyme; FIPRONIL 9.8% / S-METHOPRENE 8.8% / PYRIPROXYFEN 0.25% TOPICAL SOLUTION; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Feb-2017*	10-May-2018	13 Month(s)	D-C	Suspected Lack of Efficacy Claim: On 06 Jun 2019, the veterinary clinic staff reported the following event for Abigail , a 3 year old (born 14 Jul 2015), 38.0 pound, spayed female Australian Cattle Dog. 22 Feb 2017*: She began receiving FRONTLINE PLUS DOG 23-44 LBS (lot unknown) one dose applied topically once monthly four times on unknown dates with the following purchase history: 22 Feb 2017 (4 doses). 24 Mar 2017: She was diagnosed Lyme antigen negative via a routine 4Dx test. She received a Zoetis Lyme 1 mL SC in the left pelvic limb on 24 Mar 2017 and 19 Apr 2017. 18 Apr 2018*: She began receiving FRONTLINE GOLD DOG 23-44 LBS (lot unknown) one dose applied topically once monthly eight times on unknown dates with the following purchase history: 18 Apr 2018 (4 doses) and 22 Sep 2018 (4 doses). 10 May 2018: She was diagnosed Lyme antigen positive via a routine 4Dx test. A Quant C6 was performed with a result of 35. Treatment was initiated with doxycycline. She received a RECOMBITEK LYME 1 mL SC in the left pelvic limb on 10 May 2018 (42223, 08 Nov 2019) and 06 Jun 2019 (42237, 16 Jan 2021). 07 Dec 2018: A recheck Quant C6 was performed with a result of <10. 06 Jun 2019: She was diagnosed Lyme antigen positive via a routine 4Dx test. A Quant C6 has not been performed. No

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											treatments have been initiated. Her current condition is ongoing. She has a pertinent medical history of Lyme disease. No further medical information expected. UPDATE 14 June 2019: Quantitative C6 was <10 on 07 June 2019.
06-Jun-2019	UAE; 19US032087; -; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **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	09-May-2019	06-Jun-2019	4 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 06 Jun 2019 while inquiring if FRONTLINE PLUS 45-88 LB (lot, expiration unknown) could be given in less than 30 days post previous administration, an animal owner reported the following event in a female German Shepherd dog. All other signalment unknown. 09 May 2019: The animal owner administered 1 vial of FRONTLINE PLUS 45-88 LB (lot, exp uknown). 06 Jun 2019: The canine has a live unengorged tick on neck. Canine has access to outdoors and lives in the country. No further information provided nor expected.
06-Jun-2019	UAE; 19US032088; FL; U.S.A	**Species:** Canine **Breed:** Blue Heeler **Sex:** M **Sex qualifier:** - **Age:** 2.00 Year(s) **Weight:** 40 lbs	4	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	01-May-2019	05-Jun-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 6 Jun 2019, the owner reported the following event for Trigger, a 40 pound, 2 year old, male neutered, Blue Heeler. 1 Jun 2019: One vial of the FRONTLINE PLUS DOG 23-44 LBS (S61009AL) was applied topically in between the shoulder blades by the owner. 5 Jun 2019: The owner noticed a large amount of fleas on the pet. The dog is outdoor only. The pet has access to an open yard of 5 acres were wildlife is sometimes seen. This is the first time the owner has fleas on the pet. The owner has used FRONTLINE 1 May 2019. There is 2 cats and 1 dog in the home that are treated with FRONTLINE and are not having any issues with fleas.The owner has bathe the pet twice in Dawn since applying the first dose in May 2019. No further medical information is expected.
06-Jun-2019	UAE; 19US032115; -; U.S.A	**Species:** Canine **Breed:** Whippet **Sex:** F **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 18 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** PO-Oral **Was the product used ok?:** No (Overdose)	04-Jun-2019	05-Jun-2019	1 Day(s)	D-C	Suspected Adverse Event: On 6 Jun 2019, the veterinarian reported the following event for event for Madden, a 18 pound, 14 year old, female spayed, Whippet. 4 Jun 2019: 1 vial of FRONTLINE PLUS DOG 23-44 LBS (lot and expiration unknown) was applied to the dog in one area between the shoulder blades. 5 Jun 2019: The dog was not acting herself, unsteady and having vestibular issues. 6 Jun 2019: She was seen by the veterinarian, blood work was done the results were fairly normal. The symptoms are ongoing. The dog has been on FRONTLINE long term, unknown start date. No further medical information.
06-Jun-2019	UAE; 19US032133; MS; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various **Sex:** F **Sex qualifier:** Neutered	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	23-May-2018*	30-May-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 6 Jun 2019, the pet owner reported the following event for 2 dogs, females neutered, 10-14 pounds, 7-11years old, Mixed breeds/ various breeds. Unknown date: The dogs get a shot of heartworm prevention once every 6 months. 23 May 2019*: The pet owner applied one dose of FRONTLINE

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		Age: 7.00 Year(s) **Weight:** 10.000 - 14 lbs				**used:** Heartworm prevention shot; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					PLUS DOG 5-22 LBS (lot number unknown) topically to skin between the shoulder blades of the dogs on monthly basis year round. 30 May 2019*: The pet owner first noticed 1-5 fleas on the dogs. 6 Jun 2019: The pet owner bathed the dogs with unknown shampoo. The dogs were in good health at time of application. The dogs were not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen fleas in the home jumping and biting her. The dogs have no history of skin problems or any other issues with topical treatments. The dogs have not had flea problem before in the past. The dogs have not received any other topical treatments. The dogs are indoors and outside in fenced yard. The current status of the dogs are unknown. No further medical information.
06-Jun-2019	UAE; 19US032138; MI; U.S.A	**Species:** Canine **Breed:** Dachshund **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 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?:** Yes	03-Jun-2019	06-Jun-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 6 Jun 2019, the owner reported the following event for Miguver, 14 year old , 17 pound, neutered male, Dachshund canine. 3 Jun 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S62502AW) was applied between the shoulder blades. 6 Jun 2019: The owner found 4 deer ticks attached to the pet. The owner removed the ticks and they were still alive. The dog has access to a wooded area. The dog has received the product before on unknown dates and experienced the same issue. There are no other pets in the household. No further medical information is expected.
06-Jun-2019	UAE; 19US032174; NC; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Chocolate) **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 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	05-Jun-2019	05-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 6 Jun 2019 the pet owner reported the following event for an unknown 9 year old 90 pound male neutered Retriever (Labrador, Chocolate). *2010: The owner applied 1 vial of FRONTLINE PLUS DOG 89-132 LBS (P62005AR) to the skin and fur between the shoulder blades for the first time ever and repeated on a monthly and year round basis thereafter. 5 Jun 2019: While applying the product the owner noticed 1 flea and gave a flea bath and washed all bedding. There are no other pets in the home. There is a yellow lab that visits weekly but is treated with an unknown product. The owner is not noticing any flea activity inside the home. The dog goes outside into a fenced back yard for recreational time and is walked 2 times per day, off leash through the neighborhood. Owner will give a call if further fleas are noticed. No further medical information expected.
06-Jun-2019	UAE; 19US032177; TX; U.S.A	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** F **Sex qualifier:** - **Age:** 2.00 Year(s) **Weight:** 22 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Hartz UltraGuard Shampoo; **Route:** Topical / Cutaneous **Was the**	15-Apr-2019	25-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 6 Jun 2019 the pet owner reported the following event for Lucy, a 2 year old (born 15 Sep 2016), 22 pound, intact female Jack Russell Terrier. 15 Apr 2019: Started on FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown), 1 dose, topically, intrascapular once monthly. The pet owner stated no fleas were seen at the time of the first application. 25 Apr 2019: The pet owner began seeing a moderate amount of fleas on the canine. 15 May 2019: The most recent dose was applied. 5 Jun 2019: The pet owner bathed the canine with Hartz UltraGuard Shampoo. Currently, the pet owner states he is still seeing a moderate

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						product used ok?: Yes					amount of fleas on the canine. The canine has access to the lawn with no wooded areas and spends the majority of the time in the home. One feline also lives in the home that is on FRONTLINE PLUS CATS and is not exhibiting any fleas at his time. No further medical information is expected.
06-Jun-2019	UAE; 19US032182; PA; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **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	23-May-2019	23-May-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 6 Jun 2019, the pet owner reported the following event for Rango a male neutered, 13 pound, 5 year old, Chihuahua. 23 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S62502AW) topically to skin between the shoulder blades of Rango for the first time this year. After unknown duration of time post application the pet owner noticed Rango with red spot on the base of his tail. 6 Jun 2019: Rango was in good health at time of application. Rango was not presented to veterinarian. Fleas were on Rango at time of application with 1-2* present on his body. Rango has not had any other products at the same time as the FRONTLINE PLUS DOG 5-22 LBS application. Rango does not have history of drug or vaccine reactions. Rango has had FRONTLINE prior to reaction on seasonal basis May- September months. Rango is indoors and outside. Rango shares home with one other dog that is treated with FRONTLINE PLUS DOG 89-132 LBS (R62309AR) that has same issue with case number 19US32333. Rango also shares home with one dog that is not having a issue that is treated unknown FRONTLINE product. Rango is currently at home with ongoing issue. No further medical information.
06-Jun-2019	UAE; 19US032196; TX; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 11 lbs	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	16-May-2019*	18-May-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 6 Jun 2019, a pet owner reported the following event for Radar, an approximately 10 year old, 11* pound, neutered male Domestic Shorthair. 1 Jun 2018*: The cat began receiving monthly, year round applications of FRONTLINE PLUS CATS (Lot Unknown) topically between the shoulder blades at the base of the neck, with a 6 pack purchased on 13 May 2019 from Amazon. 16 May 2019*: The most recent application of FRONTLINE was applied. 18 May 2019*: The pet owner noticed that the cat was scratching and saw 10-15 live fleas on the cat. There are 4 other cats in the home that are treated with FRONTLINE and have fleas. No signalment was provided for these cats. The cats are indoor only. The pet owner stated that fleas are jumping on her but she is not getting bit. She has treated the inside of her home with a fogger. The pet owner has used FRONTLINE purchased from Amazon in the past without any issues and is wondering if this is a bad batch. No further information expected.
06-Jun-2019	UAE; 19US032198; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **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**	31-May-2019	01-Jun-2019*	1 Day(s)	D-D	Suspected Adverse Event and Lack of Efficacy Claim: On 6 Jun 2019, the owner reported the following event for a 10 pound canine (all other signalments unknown). 31 May 2019: Started on 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) topically between the shoulder blades by the owner. The dog had fleas prior to the first application. 1 Jun 2019*: The owner was still seeing a large amount of fleas on the dog. The dog also had a sore at the application site. 3 Jun 2019*: The sore went away. The dog has not been seen by a veterinarian or given any treatment. The owner is still seeing a large amount of fleas on the

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						product used ok?: Yes					dog. There are no fleas in the home. The dog goes outside for potty breaks in an open yard with lots of trees and bushes. No further medical information expected.
06-Jun-2019	UAE; 19US032211; CA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 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?:** No (Treatment / vaccination program not respected)	01-Mar-2019	06-Jun-2019	5 Week(s) 1 Day(s)	D-D	Suspected Lack of Efficacy Claim: 06 Jun 2019: An owner reported the following event in Whiskers; a 10 year old, 8 pound, spayed, female, Domestic Long Hair cat. 01 Mar 2019: The owner administered one vial of FRONTLINE PLUS FOR CATS (R40711AW) (3 pack) at the base of the neck. There were numerous fleas seen at the time of application. 14 Mar 2019: The owner saw fleas on the cat. It is unknown if fleas were seen in the house. 01 Apr 2019: The owner administered a vial from the same pack at the base of the neck. Fleas were still seen on the cat. 01 May 2019: The owner administered a vial from the same pack at the base of the neck. Fleas were still seen on the cat. 06 Jun 2019: The owner saw fleas on the cat. There are no other animal in home. The cat is indoor only. No further medical information available.
06-Jun-2019	UAE; 19US032250; CT; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 8.72 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Benadryl; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Jun-2019	03-Jun-2019	0 Day(s)	D-C	Suspected Adverse Event: On 6 Jun 2019, a veterinarian reported the following event for Toto, a 12 year old 872 pound, male neutered Maltese. Unknown Date: The dog started using FRONTLINE PLUS DOG 5-22 (S60302) topically between the shoulders without issue. 2 Jun 2019 and 3 Jun 2019: The owner gave Benadryl. 3 Jun 2019: The owner applied FRONTLINE PLUS and an unknown amount of time after (no time frame was given to the reporter) the dog was found stiff and disoriented. 6 Jun 2019: The owner bathed the dog, the dog was trembling and still stiff and disoriented. The DVM reports the dog has a heart murmur, bad teeth, allergies and multiple health issues. During examination the dog had neck pain and delayed knuckling and believes this may be IVDD. The dog is being treated with Gabapentin. No further medical information expected. UPDATE 6 Jun 2019: Attending's level of suspicion is low and believes signs are related to intervertebral disc disease. Nor further medical information expected.
06-Jun-2019	UAE; 19US032267; MD; U.S.A	**Species:** Canine **Breed:** Greyhound **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 73 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-Jun-2019	05-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 6 Jun 2019, a pet owner reported the following event for Nahla, an 11 year old (born 7 Jun 2008), 73 pound, spayed female Greyhound. 5 Jun 2019: The owner applied 1 dose of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) topically and later in the afternoon she was shaking and panting 6 Jun 2019: The dog began vomiting and had continnued shaking and panting. No treatment has been given at this time. Nahla was previously on FRONTLINE PLUS on an unknown date without issue. No further medical information expected.
06-Jun-2019	UAE; 19US032312; PA; U.S.A	**Species:** Feline **Breed:** Himalayan **Sex:** U **Sex qualifier:**	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE	21-Oct-2018*	22-Oct-2018*	N/A	D-D	Suspected Lack of Efficacy Claim: On 6 Jun 2019, the owner reported the following event for two, 9 month old, 10 pound, Himalayan felines (all other signalments unknown). 21 Oct 2019*: The owner started to notice a moderate amount of

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		Unknown **Age:** 9.00 Month(s) **Weight:** 10 lbs				12% SPOT ON **Other products used:** Vets Best Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					fleas on the cats. The cats began receiving monthly doses of FRONTLINE PLUS CATS (S41003AW) topically between the shoulder blade. 22 Oct 2018*: The flea issue persisted. 21 May 2019*: The most recent vial was applied. The flea issue has continued. The owner is now finding a large number of fleas on the pet. The owner is also finding fleas in the household. 22 May 2019*: The owner bathed the cats with Vets Best shampoo. 6 Jun 2019: The issue is still ongoing. The cats are strictly indoor. There are no other pets in the household. No further medical information is expected.
06-Jun-2019	UAE; 19US032321; TN; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 45 - 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	16-May-2019	16-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 6 Jun 2019, the pet owner reported the following event for Bailey, a 45 to 50 pound*, male neutered, Large crossbred (>20 kg). 16 May 2019:It is unknown if the dog was having an issue with fleas. 1 vial of FRONTLINE PLUS DOG 45-88 LBS(S6211AL) was applied to the dog in one area between the shoulder blades. The owner has been seeing a medium amount of fleas on the dog since the application. The dog goes out for potty breaks and recreation in fenced in yard. The dog has no history of skin issues and has not had a bath recently. There is one other dog in the home that was treated with FRONTLINE and has had an issue with fleas since the most recent application 16 May 2019 ,see case 19US035818. The owner has been treating the dog with FRONTLINE PLUS year round since 2017*.There is one cat in the home treated with FRONTLINE PLUS CATS see case 19US035604. No further medical information is expected.
06-Jun-2019	UAE; 19US032333; PA; U.S.A	**Species:** Canine **Breed:** Hound Breeds (200 Series) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 129 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-May-2019	23-May-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 6 Jun 2019, the pet owner reported the following event for Ruger a male neutered, 129 pound, 4 year old, Hound Breeds. Unknown dates: Ruger had red spot at the base of tail prior to product application. 23 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 89-132 LBS (R62309AR) topically to skin between the shoulder blades of Ruger for the first time this year. After unknown duration of time post application the pet owner noticed Ruger with red spot on the base of his tail that got worse. 6 Jun 2019: Ruger was in good health at time of application. Ruger was not presented to veterinarian. Ruger has not had any other products at the same time as the FRONTLINE PLUS DOG 89-132 LBS application. Ruger does not have history of drug or vaccine reactions. Ruger has had FRONTLINE prior to reaction on seasonal basis May- September months. Ruger is indoors and outside. Ruger shares home with one other dog that is treated with FRONTLINE PLUS DOG 5-22 LBS (S62502AW) that has same issue with case number 19US032182. Ruger also shares home with one dog that is not having a issue that is treated unknown FRONTLINE product. Ruger is currently at home with ongoing issue. No further medical information.
07-Jun-2019	UAE; 19US032348; TX; U.S.A	**Species:** Canine **Breed:** Australian Terrier **Sex:** F **Sex qualifier:**	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	17-May-2019	30-May-2019	13 Day(s)	D-D	Suspected Adverse Event: On 7 Jun 2019, the pet owner reported the following event for Lola a female spayed, 12 pound, 13 year old, Australian Terrier. Unknown dates: The pet owner has used FRONTLINE PLUS DOG 5-22 LBS previously a few years ago.

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		Neutered **Age:** 13.00 Year(s) **Weight:** 12 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					17 May 2019: Prior to application, the pet owner noticed Lola scratching with an unknown amount of fleas present. The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S61017AL) topically to skin between the shoulder blades of Lola for the first time this year. 30 May 2019: The pet owner noticed increase in scratching with no fleas seen on the pet. Lola was in good health at time of application. Lola was not presented to veterinarian. Lola has not had any other products at the same time as the FRONTLINE application. Lola does not have history of drug or vaccine reactions. Lola shares home with one other dog that is treated with unknown FRONTLINE product that has no issues. Lola is currently at home with ongoing issue. No further medical information.
07-Jun-2019	UAE; 19US032352; GA; U.S.A	**Species:** Canine **Breed:** Border Collie **Sex:** F **Sex qualifier:** Neutered **Age:** 20.00 Month(s) **Weight:** 71 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Nemoil; Earth Animal Nature's Protection; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	31-May-2019*	05-Jun-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Jun 2019, the animal owner reported the following event for Annabelle , a 20 month old, 71 pound, spayed female, Border Collie Bernese Mountain Dog Mix. 31 May 2019*: She began receiving FRONTLINE PLUS 45-88 LBS (R62001AR) monthly. 5 Jun 2019: The owner noticed fleas/ticks. The dog does frequent outside often. She began itching as the fleas came back. The owner is not seeing fleas in the house or on her person. The owner states she bathes the dog weekly and it will also occasionally go into rivers and creeks. She also puts Nemoil on her dog, her dog also use Earth Animal Nature's Protection, and the owner stated she puts Nematodes in the yard to help stop fleas. The owner states she is seeing 5-15 fleas a day on the animal. The owner stated the tick she found was almost dead and the exact date is unknown as to when she found it, but she claims it was after the last application. 6 Jun 2019*: She presented to the veterinary clinic. The owner was given a NEXGARD to give to the animal, it is unclear if they have provided this to the animal yet. There is 1 outside cat at the house. She has used FRONTLINE PLUS since 25 Apr 2019. Further medical history is unknown, as the owner had to leave the call. No further medical information expected.
07-Jun-2019	UAE; 19US032403; OH; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** 16.00 Month(s) **Weight:** 88.0 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-May-2019*	07-Jun-2019	23 Day(s)	D-C	Suspected Lack of Efficacy Claim: On 07 Jun 2019, the animal owner reported the following event for Casey, a 16 month old*, 88.0 pound, spayed female Golden Retriever. 15 May 2019*: She received FRONTLINE PLUS DOG 45-88 LBS (S62518AX) one dose applied topically between the shoulders for the first time. 07 Jun 2019: She presented to the veterinary clinic for routine examination. She was diagnosed faint Anaplasmosis antigen positive via an unknown type of test. Treatments have not been initiated. Her current condition is ongoing. There are no other pets in the household. No further medical information expected.
07-Jun-2019	UAE; 19US032409; MI; U.S.A	**Species:** Canine **Breed:** Schnauzer (Miniature) **Sex:** M **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	05-Jun-2019	05-Jun-2019	0 Day(s)	D-C	Suspected Adverse Event: On 7 Jun 2019, the pet owner reported the following event for Rambo a male neutered, 27 pound, 12 year old, Schnauzer (Miniature) 5 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 23-44 LBS (lot number unknown) topically between

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		Neutered **Age:** 12.00 Year(s) **Weight:** 27 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					the shoulder blades of Rambo for the first time but did not get onto the skin just hair. After approximately 8* hours post application the pet owner noticed Rambo experience lethargy not wanting to eat, shaking, tremors, and having a choking/vomit type sound. Rambo was in good health at time of application. Rambo was not presented to veterinarian. Rambo has not had any other products at the same time as the FRONTLINE PLUS DOG 23-44 LBS application. Rambo did not have fleas at time of application. Rambo does not have history of drug or vaccine reactions. Rambo has not had FRONTLINE PLUS prior to reaction. Rambo is currently at home with ongoing issue. No further medical information.
06-Jun-2019	UAE; 19US032420; MS; U.S.A	**Species:** Canine **Breed:** Whippet **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	23-May-2019*	23-May-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 6 Jun 2019, the pet owner reported the following event for a 36 pound, female spayed, Whippet. All other signalments unknown. 23 May 2019*: The dog was having an issue with fleas. 1 vial of FRONTLINE PLUS DOG (S61701AL) was applied to the dog in one area between the shoulder blades. The owner has been seeing a large amount of fleas on the dog every day since the application. The owner treats year round and monthly with FRONTLINE PLUS. The dog goes out for potty breaks and recreation in a yard no urban wildlife seen. There are no fleas in the home. The dog has no history of skin issues and has not had a bath recently. There is one other dog in the home having an issue with fleas and is treated with FRONTLINE, see case 19US32422. No further medical information is expected.
06-Jun-2019	UAE; 19US032422; MS; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** - **Age:** - **Weight:** 96 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)	23-May-2019*	23-May-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 6 Jun 2019, the pet owner reported the following event for a 96 pound, intact male, German Shepherd Dog. All other signalments unknown. 23 May 2019*: The dog was having an issue with fleas. 1 vial of FRONTLINE PLUS DOG (S61701AL) was applied to the dog in one area between the shoulder blades. The owner has been seeing a large amount of fleas on the dog every day since the application. The owner treats year round and monthly with FRONTLINE PLUS. The dog goes out for potty breaks and recreation in a yard no urban wildlife seen. There are no fleas in the home. The dog has no history of skin issues and has not had a bath recently. There is one other dog in the home having an issue with fleas and is treated with FRONTLINE, see case 19US032420. No further medical information is expected.
07-Jun-2019	UAE; 19US032423; -; U.S.A	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 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-Jan-2018*	07-Jun-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Jun 2019, the owner reported thef ollowing event for Coco, a 15 pound, 4 year old*, spayed female Miniature Poodle mix. 2018*: Coco started on FRONTLINE PLUS DOG 0-22 LBS (S62502)(invalid) seasonally. 25 May 2019: The most recent dose was applied in an unknown location. 7 Jun 2019: The owner reported that as she was bathing Coco, she noticed 2-3 dead fleas and flea dirt. Coco does take the usual walks and visits to the dog park. It is unknown if there are any other dogs in the home. 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
07-Jun-2019	UAE; 19US032436; MN; U.S.A	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 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	06-Jun-2019	06-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 7 Jun 2019, a clinic staff member reported the following event for Kali, an 11 year old (born 1 May 2008), 5 pound, spayed female Miniature Poodle. 6 Jun 2019: The dog received 1 application of FRONTLINE PLUS DOG 5-22 LBS (Lot Unknown) topically between the shoulder blades around 3 pm. Right after the application the dog began experiencing loose stools and seemed to be a little lethargic. 7 Jun 2019: The dog presented to the clinic for examination. No abnormalities were noted and no treatments were provided. It is unknown if the dog recovered. The dog is not on any other medications. The dog had previously received FRONTLINE on 6 May 2019* without any adverse events noted. No further medical information expected.
07-Jun-2019	UAE; 19US032439; CA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 2 - 10 lbs	5	5	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** DAWN; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	24-May-2019	26-May-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Jun 2019, the owner reported the following event for 5 felines, weighing 3-10 pounds, all other signalment unknown. 24 May 2019: FRONTLINE PLUS CATS (S40117AW) was applied topically in between the pets' shoulder blades by the owner. 26 May 2019: A large amount of fleas were seen on the pets. The cats are strictly indoor and the owner fosters animals throughout the year. No indoor fleas seen. No wildlife is seen in the area. The owner uses FRONTLINE as needed at an unknown frequency, this is the first dose of the season. The owner has bathe the pets in Dawn at and unknown frequency. The owner also has dogs see additional case 19US035282. No further medical information expected.
07-Jun-2019	UAE; 19US032440; MO; U.S.A	**Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** X **Sex qualifier:** Mixed **Age:** 7.00 Year(s) **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	19-May-2019	21-May-2019*	N/A	D-D	Suspected Adverse Event: On 7 Jun 2019, the pet owner reported the following event for Skipper a female spayed, 7 year old, feline mixed/various breeds, other signalment unknown. The pet owner also reported the following event for Toodles a female spayed , 7 year old, feline mixed/various breeds, other signalment unknown. The pet owner also reported following event for Dude a male intact, 7 year old, feline mixed /various breeds, other signalment unknown. 19 May 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S40117AW) topically to skin between the shoulder blades monthly on year round basis to Skipper and Toodles . After approximately 1-2* days post application the pet owner noticed the cats hair fell off at the application site along with start of itching . 28 May 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S40117AW) topically to skin between the shoulder blades monthly on year round basis to Dude. After approximately 1-2* days post application the pet owner noticed Dude's hair fell off at the application site along with start of itching. 7 Jun 2019: The cats were in good health at time of application. The cats were not presented to veterinarian. The cats have not had any other products at the same time as the FRONTLINE PLUS CATS application. The cats have not had history of drug or vaccine reactions. The cats were indoors and outside. The cats are currently at home with ongoing issue. No further medical information.
07-Jun-2019	UAE; 19US032459; TX; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M	1	1	0	**Product used:** FIPRONIL 10%/S	17-May-2019*	01-Jun-2019*	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Jun 2019 the pet owner reported the following event for a 5 pound male Chihuahua of unknown further signalment. 17 May 2019*: The pet owner applied FRONTLINE PLUS DOG

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		Sex qualifier: Unknown **Age:** - **Weight:** 5 lbs				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose)					5-22 LBS (product unsubstantiated) (lot and expiration unknown), 0.75 dose, topically to an unknown application site for the first time. 1 Jun 2019*: The pet owner reported seeing approximately 3 fleas on the canine. 7 Jun 2019: The pet owner is currently seeing approximately 3 fleas on the canine. The canine spends the majority of the time inside the home and is taken to a dog park an unknown number of times per month. There are no other pets in the household. No further medical information is expected.
07-Jun-2019	UAE; 19US032492; AL; 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:** PO-Oral **Was the product used ok?:** Unknown to Company	06-Jun-2019*	07-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 7 Jun 2019, the pet owner reported the following event for a feline with unknown signalment. 6 Jun 2019*: Another cat in the home received FRONTLINE PLUS CATS (lot unknown) topically. 7 Jun 2019: This cat who did not get product applied is drooling, foaming at the mouth and seems listless. The pet owner offered some milk and the cat only took a couple licks. The cat has also been hiding under the bed all day. Owner suspects cat ingested product but it cannot be confirmed if the cat ingested the product or licked it off the other cat in the home. The cat has not presented to the veterinary clinic. No further medical information expected.
07-Jun-2019	UAE; 19US032495; NY; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 18 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Flea Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Apr-2019	07-Jun-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Jun 2018, the owner reported the following event for Riley, 11 year old , 18 pound, spayed female, Maltese Poodle mix canine. 27 Apr 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S60808AL) was applied between the shoulder blades for the first time this season. 24 May 2019: The owner found a small number of fleas on the pet. The owner bathed with a flea shampoo. 27 May 2019: Another vial was applied. 7 Jun 2019: The owner found 6 fleas on the pet. The issue is still ongoing. The dog goes out for potty breaks in a fenced in area and has access to the neighborhood for walks. The dog has received the product before on prior unknown dates with no issue. There are no other pets in the household. No further medical information is expected.
07-Jun-2019	UAE; 19US032546; VA; U.S.A	**Species:** Feline **Breed:** Ragdoll **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 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 product used ok?:** Yes	04-Apr-2019	08-Apr-2019	4 Day(s)	D-D	Suspected Adverse Event: On 07 Jun 2019, Animal owner reported the following adverse event for Loki, a 8 year old, 12 pound, neutered male ragdoll. 04 Apr 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (Lot S40717AW) topically between the shoulder blades for the first time. 08 Apr 2019: The cat developed alopecia at the application site. 10 Apr 2019: The cats hair color started to change color. The color went from a dark brown to a light tan. The cat continued to lose hair down his back and his tail for several weeks. 31 May 2019: The cat presented for an exam. Bloodwork was performed with all values within normal limits. The cat was not treated with any medications. 07 Jun 2019: The patient presented for a second exam for non-improving symptoms. A flea allergy test was performed and was negative.

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											There are no other pets in the home. No further information expected at this time. UPDATE 11 Jun 2019: As reported by the veterinarian, the owner reported thinning hair coat along the tail that started on an unknown date after 04 Apr 2019. No further information is expected.
07-Jun-2019	UAE; 19US032581; PA; U.S.A	**Species:** Canine **Breed:** Lhasa Apso **Sex:** M **Sex qualifier:** Neutered **Age:** 13.50 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-Jun-2019	03-Jun-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Jun 2019, the pet owner reported the following event for Dino a male neutered, 15 pound, 13.5 year old, Lhasas Apso. 1 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S63009BL) topically to skin between the shoulder blades to the body of Dino monthly year round. 3 Jun 2019: The pet owner noticed 15+ fleas on the body of Dino. Pet owner gave Dino unknown flea spray. 5 Jun 2019: The dog was bathed with Hartz flea and tick shampoo. 7 Jun 2019: Dino was in good health at time of application. Dino was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. Dino has no history of skin problems or any other issues with topical treatments. Dino has not had flea problem before in the past. Dino has not received any other medications but has received unknown flea spray. Dino is indoors and outside for bathroom breaks. The current status of Dino is unknown. No further medical information.
05-Jun-2019	UAE; 19US032603; KY; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various **Sex:** X **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 90 - 100 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-May-2019*	01-Jun-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 5 Jun 2019, the pet owner reported the following event for Gavin, a male neutered, 100 pound, 4 year old, German Shepherd Dog. The pet owner also reported the following event for Jessie a female spayed, 90 pounds, 10 year old, Pitbull. 1 May 2018*-1 May 2019*: The pet owner applied one dose of FRONTLINE PLUS DOG 89-132 LBS (R60716AR) topically to skin between the shoulder blades of the dogs on monthly basis year round. 1 Jun 2019: The pet owner continued to see 5-15 fleas on the dogs. 7 Jun 2019: The dogs were in good health at time of application. The dogs were not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has seen fleas in the home jumping and biting her. The dogs have no history of skin problems or any other issues with topical treatments. The dogs have had flea problem before in the past. The dogs have not received any other medications or topical treatments. The dogs are indoors and outside. The current status of the dogs are unknown. No further medical information.
07-Jun-2019	UAE; 19US032615; VT; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 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 product used**	06-Jun-2019	07-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 7 Jun 2019, the owner reported the following event for Oliver, 1 year old, 12 pound, neutered male, Domestic Longhair Feline. 6 Jun 2019: One vial of FRONTLINE PLUS CATS (S40603AW) was applied between the shoulder blades for the very first time. 7 Jun 2019: The next morning the cat became very lethargic. The cat did not present to the clinic and no treatment was provided. The symptoms are still ongoing. There is one other cat in the household that did not receive the product and is asymptomatic. No further medical information is expected.

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						ok?: Yes					
07-Jun-2019	UAE; 19US032661; VA; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 9 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Nobivac Lepto; Vanguard Lyme; Merck Intranasal Bordetella; ProHeart; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	07-Jun-2019	07-Jun-2019	0 Day(s)	D-C	Suspected Adverse Event: On 7 Jun 2019, the veterinarian reported the following event for Teddy, a 10 year old, 9 pound, neutered male, Yorkshire Terrier. 6 Jun 2019: The patient was vaccinated by a veterinarian with Nobivac Lepto, Vanguard Lyme, Merck Intranasal Bordetella, and also received an injection of ProHeart. The volumes, routes, and locations of injection are unknown. At the time of vaccination, he was presented with dental calculus and luxating patellas, but was otherwise fine. 7 Jun 2019: The pet owner accidentally applied one vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) topically between the shoulder blades. An unknown duration (though no more than three hours) following product application, the pet owner felt Teddy was warm to the touch and the skin on his ventral abdomen was red. The pet owner subsequently washed the application site with an unknown product. When Teddy presented to the reporter, his body temperature was WNL and other than the skin on his ventral abdomen still appearing erythematous, his physical exam was WNL. No further treatment has been given for the ongoing symptoms. The patient has a history of experiencing soreness after receiving unknown vaccines. No further medical information expected.
07-Jun-2019	UAE; 19US032673; KS; U.S.A	**Species:** Canine **Breed:** Siberian Husky **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 70 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	07-Jun-2019	07-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 7 June 2019, the owner reported the following event for Mika, 8 years old, 70 pounds, Neutered male, Siberian Husky. 7 June 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S61202AX) was applied between the shoulder blades, by the pet owner. An unknown amount of time later the fur started to fall out on the application area. The pet owner stated that the area was red and irritated, the undercoat and overcoat had fallen out. The dog was bathed with Neutrogena body wash and warm water. No further medical information is expected.
10-Jun-2019	UAE; 19US032711; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** EPRINOMECTIN 0.4% / PRAZIQUANTEL 8.3% SOLUTION; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-May-2019	10-May-2019	4 Day(s)	D-D	Suspected Adverse Event: On 10 Jun 2019, Animal owner reported the following event for Lincoln, a 13 year old, 10 pound, neutered male domestic Shorthair cat. 06 Apr 2019: The pet owner applied the entire contents of CENTRAGARD 5.6-16.5 LBS (Lot: CUS003NAA, Feb 2020) topically to the right side of the back of the neck for the first time. The full contents of FRONTLINE PLUS FOR CATS (Lot unknown) was applied topically to the left side of the neck. 06 May 2019: The pet owner applied the entire contents of CENTRAGARD 5.6-16.5 LBS (Lot: CUS003NAA, Feb 2020) topically to the right side of the back of the neck and the full contents of FRONTLINE PLUS FOR CATS (Lot unknown) was applied topically to the left side of the neck. 10 May 2019: The pet owner noticed the hair color changed from black to white at the application site for CENTRAGARD. 10 Jun 2019: The pet owner stated the hair is still white. There are no other animals in the home. The pet has not been seen by a vet. No further information expected.
10-Jun-2019	UAE;	**Species:** Canine	1	1	0	**Product used:**	01-May-2019	02-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim:On 10 June 2019, the owner

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	19US032719; OH; U.S.A	**Breed:** Pomeranian **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 the following event for a Pomeranian (all other signalments unknown). 1 May 2019: The dog started FRONTLINE PLUS on a monthly basis. 1 June 2019: The most recent vial of FRONTLINE PLUS DOG 5-22 LBS (Lot unknown) was applied between the shoulder blades, by the pet owner. 2 June 2019: The dog had a moderate amount of fleas. The dog has not been bathed. The owner is not seeing any flea activity in the home. The dog goes outside for bathroom breaks. There is 1 other dog in the home using FRONTLINE PLUS as well with case 19US032719. No further medical information is expected.
10-Jun-2019	UAE; 19US032721; OH; U.S.A	**Species:** Canine **Breed:** Chowchow **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-May-2019	02-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim:On 10 June 2019, the owner reported the following event for a Chowchow (all other signalments unknown). 1 May 2019: The dog started FRONTLINE PLUS on a monthly basis. 1 June 2019: The most recent vial of FRONTLINE PLUS DOG 23-44 LBS (Lot unknown) was applied between the shoulder blades, by the pet owner. 2 June 2019: The dog had a moderate amount of fleas. The dog has not been bathed. The owner is not seeing any flea activity in the home. The dog goes outside for bathroom breaks. There is 1 other dog in the home using FRONTLINE PLUS as well with case 19US032719 No further medical information is expected.
10-Jun-2019	UAE; 19US032723; FL; U.S.A	**Species:** Canine **Breed:** Chinese Crested **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 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	31-May-2019	01-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019, the owner reported the following event for Bradley, 6 year old, 10 pound, neutered male, Chinese Crested canine. 31 May 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S62502AW) was applied between the shoulder blades for the very first time. 1 Jun 2019*: The owner found 1 flea on the dog. No fleas were noted in the household. The owner removed the flea. The dog has access to a fenced in yard. There are no other pets in the household. The owner has not bathed the pet. No further medical information is expected.
10-Jun-2019	UAE; 19US032726; CT; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 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?:** No (Species not indicated /	08-Jun-2019	09-Jun-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 10 Jun 2019, a pet owner reported the following event for Lilly, a 12 year old, 8 pound, spayed female Chihuahua. 8 Jun 2019: The dog went outside and the grandson applied 1 dose of FRONTLINE PLUS CATS (H40801AW) topically between the shoulder blades by accident. 9 Jun 2019*: The dog is not eating as enthusiastically as she normally does. She is wanting the pet owner to hand feed her. She is acting fine otherwise. No further medical information expected.

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						recommended)					
10-Jun-2019	UAE; 19US032737; AL; U.S.A	**Species:** Feline **Breed:** Maine Coon Cat **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 17 - 18 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)	01-May-2019	06-Jun-2019*	5 Week(s) 1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019, the pet owner reported the following event for Mittens, 17 to 18 pound*, male neutered, Maine Coon Cat. All other signalments unknown. 1 May 2019: 1 vial of FRONTLINE PLUS CATS(R4118AW) was applied to the cat in one area between shoulder blades. 6 Jun 2019*: The owner found and removed 1 tick from the cat. The cat is indoor/outdoor. The owner has been treating with FRONTLINE year round since 2016*. There are two other cats in the home treated with FRONTLINE. No further medical information is expected.
10-Jun-2019	UAE; 19US032749; TN; U.S.A	**Species:** Canine **Breed:** Papillon **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 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	30-May-2019	03-Jun-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019, the pet owner reported the following event for Oliver, an 11 year old, 10.5 pound, neutered male Papillon. 2018*: The dog began receiving monthly doses of FRONTLINE PLUS DOG 5-22 LBS (S61017AL) applied topically between the shoulder blades with the most recent 3 pack purchased 25 April 2019. 30 May 2019: The most recent dose was administered. 3 Jun 2019: The owner observed less than 10 fleas on the dog along with flea dirt. No fleas were seen in the home although the owner observed a flea on her after sitting near the dog. Oliver goes outside only to go to the bathroom and was not bathed within 24 hours of FRONTLINE PLUS application. There are no other dogs in the home. No further medical information expected.
10-Jun-2019	UAE; 19US032776; KS; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **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:** unknown prescription shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Mar-2019	27-Mar-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019 the pet owner reported the following event for Miss Gracie a 5 year old, 85 pound, Female spayed Retreiver (Golden). *2014: The owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S62111AL) to the skin between the shoulder blades for the first time and continued on a seasonal and monthly basis on the 15th of each month except for in Nov and Dec each year. *2018: The owner began bathing the dog with an unknown prescription shampoo for dogs and repeated monthly on the 10th of each month. 15 Mar 2019: The owner applied a dose from a new package. *27 Mar 2019: The owner began noticing more than 10 fleas each day for the first time ever. 15 Apr 2019: The owner applied another dose. 16 Apr 2019: The owner continued to see more than 10 fleas each day. 15 May 2019: The owner applied the most recent dose. 16 May 2019: The owner continued to see more than 10 fleas each day. There are no other pets in the home. The owner is not seeing any indoor flea activity. The dog has access to a large fenced back yard and goes for walks on the sidewalk in the neighborhood each day. The dog does not have any skin issues. No further medical information expected.

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16-May-2019	UAE; 19US032790; -; 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	14-May-2019*	15-May-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 May 2019, the pet owner reported the following event for an unknown amount of Felines of unknown signalment. 14 May 2019*: The cats had an unknown number of fleas present. The owner applied FRONTLINE PLUS CATS (lot and expiration unknown). 15 May 2019*:The owner has still been noticing fleas since putting FRONTLINE PLUS on the cats. The owner states the cats do not go outside. The owner states she has also been vacuuming up daily except for one day since applying FRONTLINE. Further information is unknown at this time. The current status of the cats is unknown. There are multiple felines in the household, exact number is unknown. It is unknown if the cats have received FRONTLINE prior to this event. No further medical information expected. UPDATE 12 Jun 2019: Second Attempt made to collect information. No further information is expected.
10-Jun-2019	UAE; 19US032831; RI; U.S.A	**Species:** Canine **Breed:** Hound Breeds (200 Series) **Sex:** F **Sex qualifier:** Neutered **Age:** 12.50 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-May-2019	24-May-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019 an animal owner reported the following event in Delilah, a 12.5 year old, female spayed, 40 pound, hound mix. 20 May 2019: One tube of FRONTLINE PLUS DOGS 23-44 LBS (lot S60308AL) was applied between the shoulder blades. 24 May 2019: 6 live ticks of unknown species were found on the canine. 1 tick was engorged. 25 May 2019: The ticks were removed. No further information provided nor expected.
07-Jun-2019	UAE; 19US032847; CA; U.S.A	**Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** X **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 12 - 17.5 lbs	3	3	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	29-May-2019	30-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 June 2019, the owner reported the following event for Bandy, a 17.5 pound, a neutered male Domestic Mediumhair,Gipsey, a 12 year old, 17 pound, spayed female Domestic Shorthair, and Shi Shi a 6 year old, 12 pound, spayed female Domestic shorthair. 29 May 2019: The cats were scratching and had fleas for a few weeks. One application of FRONTLINE PLUS CATS (FL) (S40717A) was topically applied to the skin between the shoulder blades to each cat. 30 May 2019: The cats continued to scratch at the same level and have fleas in a small number. There are fleas in the home and the cats goes outside to a small grass yard. The cats are treated every 2 months with FL and they are not bathed. The cats have been treated all their lives with FL. There is one treated dog in the home battling fleas. No further information available. UPDATE 20 Jun 2019: After further review the multiple patient screens were removed and the information consolidated into one screen
07-Jun-2019	UAE; 19US032853; CA; U.S.A	**Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** X **Sex qualifier:**	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products**	29-May-2019	29-May-2019	0 Day(s)	D-D	Suspected Adverse Event: On 7 June 2019, the owner reported the following event for Bandy, a 17.5 pound, a neutered male Domestic Mediumhair,Gipsey, a 12 year old, 17 pound, spayed female Domestic Shorthair, and Shi Shi a 6 year old, 12 pound, spayed female Domestic shorthair. 29 May 2019: The cats were scratching and had fleas for a few weeks. The owner took out the applications of FRONTLINE PLUS

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		Neutered **Age:** 6.00 Year(s) **Weight:** 12 - 17.5 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					CATS (FL) (S40717AW). Before the treatment was given the cats ran and hid upon seeing the vial. The FL was topically applied to the skin between the shoulder blades to each cat and immediately following the treatment each cat moved in agitation as if they were being burned, no skin irritation was noticed. 30 May 2019: The reaction lasted for 12 hours and they recovered without vet assistance. Each cat has been on FL every 2 months seasonally all their lives with the same reaction each time. No further information available.
10-Jun-2019	UAE; 19US032858; -; U.S.A	**Species:** Canine **Breed:** Bloodhound **Sex:** M **Sex qualifier:** Neutered **Age:** 2.50 Year(s) **Weight:** 131 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Levothyroxine; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Jun-2019	07-Jun-2019	0 Day(s)	D-C	Suspected Adverse Event: On 10 Jun 2019 an animal owner reported the following event in Amos, a 2.5 year old, 131 pound, male neutered Bloodhound. 07 Jun 2019: 1 vial of FRONTLINE PLUS 89-132 LB (PP04361) was applied between the shoulder blades. That evening the canine would not eat his dinner. 08 Jun 2019: The canine developed dry heaving was not eating or drinking. 10 Jun 2019: The canine presented to a veterinarian for ongoing signs. At time of presentation that canine was reported to have dilated pupils, neurological, wabbling, and increased heart rate. The canine has been hospitalized and treated with intravenous fluids, and the FRONTLINE PLUS is being bathed off. The canine has a history of preexisiting thyroid issue and is currently on levothyroxine 1mg tab SID. No further information provided. UPDATE 11 Jun 2019: Per the vet: 11 Jun 2019: Neurologic signs have resolved, but pet is still anorexic. Pet is still on IV fluids. No further information at this time. UPDATE 11 Jun 2019: Per attending, a CBC and chemistry were performed. All values were normal except an elevation in the globulins. Pet is also hypothyroid and is taking levothyroxine. No further medical information available. UPDATE 12 Jun 2019: Per records received, Globulins were 5.1 g/dL (2.5-4.5). Total T4 was <1.0 ug/dL (1.0-4.0ug/dL).
10-Jun-2019	UAE; 19US032864; GA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 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	08-Jun-2019	08-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 June 2019, the owner reported the following event for Charlie, a 10 year old, 14 pound, neutered male Domestic Longhair. 8 June 2019: The cat had fleas and was itching and scratching, the owner applied one via of FRONTLINE PLUS CATS (S41108) to the skin between the shoulder blades. 9 June 2019: The cat continued to have 3-4 fleas and continued to itch and scratch. The cat is indoor and outdoor and is exposed to the woods. There are no fleas in the home and the cat doesn't have any skin issues. It is unknown if the cat has had FL in the past or if this was the first application. No further information available. UPDATE 19 JUN 2019: Per the pet owner: 19 Jun 2019: The pet owner continues to observe 3-4 fleas on the cat daily alogn with flea dirt. Since seeing fleas, he has kept the cat indoors. No further medical information expected.
10-Jun-2019	UAE; 19US032868; RI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	20-May-2019	07-Jun-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019, Animal owner called to report the following event in her dog. 20 May 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 23-44 LBS (Lot unknown) topically between the shoulder blades. 07 Jun 2019: The pet owner took her dog for a walk on the beach.

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		Age: - **Weight:** Unknown				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					The pet owner found 10 live ticks crawling on her dog and found 2 ticks crawling on her kitchen floor. 08 Jun 2019 - 09 Jun 2019: The pet owner found a few ticks attached and found 2 ticks crawling in her bed. The species have not been identified by a vet and it is unknown if there any other animals in the home. No further information expected.
10-Jun-2019	UAE; 19US032906; SC; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Neutered **Age:** 11.50 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	09-Jun-2019	10-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019, the owner reported the following event for Teddy, a 13 pound, male neutered, 11.5 year old, Maltese. 9 Jun 2019: One vial of FRONTLINE PLUS DOG 5-22LBS (S61718AL) was applied topically in between the pet's shoulder blades by the owner. 10 Jun 2019: A small amount of fleas were seen on the pets. The dog in indoor mostly and walked in the yard for potty breaks and recreation. No indoor fleas seen. Rabbits are seen in the area. The owner uses FRONTLINE since the dog was a puppy at an unknown start date. There were 2 visiting pets to the home that stayed about a week it is unsure if they were on flea prevention. No further medical information expected.
10-Jun-2019	UAE; 19US032917; OR; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 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	12-Apr-2019	01-Jun-2019*	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 June 2019, the owner reported the following event for Misty, a 9 month old, 6 pound, spayed female Domestic Shorthair. 12 May 2019: One vial of FRONTLINE PLUS CATS (FL) (R40801AW) was topically applied to the skin between the shoulder blades. A few weeks after the application (reporter doesn't have exact date) Misty was taken to the vet and she was loaded with fleas and she was scratching. Misty has been on FL for 2 months. There is some flea activity in the home. The cat is indoor but has access to outside grass on occasion. The cat doesn't have any skin issues. No further information available.
10-Jun-2019	UAE; 19US032951; CT; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 16 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown oatmeal shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-Apr-2019*	04-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019 the pet owner reported the following event for Patches a 16 pound male small crossbred (<10 kg) Canine. All other signalments are unknown. *2018: The owner applied 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S62502AW) to the skin between the shoulder blades for the first time and repeated dose on a seasonal basis thereafter. *3 Apr 2019: The owner applied the first dose of the season. The dog was scratching prior to use for an unknown amount of time. It is unknown if fleas were seen prior to use. *3 Jun 2019: The owner gave the dog a bath with an unknown oatmeal shampoo for dogs. The owner then applied the most recent dose. *4 Jun 2019: The owner began noticing large amounts of fleas. The dog has continued scratching the same amount causing fur loss all over the body. 10 Jun 2019: The owner noticed sores under the armpits from the dog scratching, the skin was alright prior to these sores. The owner applied an antibiotic ointment on the sores. There are no other pets in the home. The owner is not noticing indoor flea activity but is noticing outdoor flea activity. The dog has access to an unknown yard. No further medical information expected. UPDATE 24 Jun 2019: After further review, Adverse Reaction was

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											added as a product problem type for the concomitant oatmeal shampoo.
10-Jun-2019	UAE; 19US032959; NC; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 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	04-May-2019	04-Jun-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019 an animal owner reported the following event in 2 40 pound canines. All other signalment not provided by animal owner. 04 May 2019: FRONTLINE PLUS 23-44 LB (lot, expiration unknown) was applied per labeled instructions to both canines. No fleas seen at time of administration. 04 Jun 2019: FRONTLINE PLUS 23-44 LB was applied per labeled instructions to both canines. Fleas were seen at time of administration. 10 Jun 2019: The animal owner reports still seeing fleas. Neither of the canines have been bathed. There is a cat in the household that is on FRONTLINE PLUS CATS. The animal owner has sprayed Ortho home defense to the yard. No further information provided nor expected.
10-Jun-2019	UAE; 19US032964; GA; U.S.A	**Species:** Canine **Breed:** Greyhound **Sex:** U **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **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	01-Jun-2019	10-Jun-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019, Animal owner reported the following event for her 2 greyhounds who are between the ages of 7 and 11 years old. *01 May 2019: The pet owner moved into a new house that had a flea issue. The house and yard were treated by unknown products. 01 Jun 2019, The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 5-22 LBS (Lot unknown) topically to the back of the neck. It is unknown if the dogs had fleas prior to the use of product. *10 Jun 2019: The pet owner saw 40 fleas alive on the dogs. The pet owner applied skin so soft to the dogs. All additional information is unknown due to the pet owner declining to provide specific information. No further information expected.
10-Jun-2019	UAE; 19US032984; IN; 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-Jun-2019*	02-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 June 2019, the owner reported the following event for a canine(all other signalments unknown). May 2019: The dog started on FRONTLINE PLUS DOG 5-22 LBS (lot unknown and product unsubstantiated) 1 June 2019*: The most recent vial of FRONTLINE PLUS was applied between the shoulder blades, by the pet owner. 2 June 2019*: The dog had fleas. It is unknown if the dog gets bathed or not. The owner is not seeing ay fleas activity in the home. The dog goes outside for bathroom breaks. It is unknown if fleas were seen before application of the product. No further medical information is expected.
10-Jun-2019	UAE; 19US032988; -; 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**	24-May-2019	10-Jun-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019, a pet owner reported the following event for a feline of unknown signalment. 24 May 2019: The owner applied a dose of FRONTLINE PLUS CATS (lot unknown) topically. The owner is not sure if there were live fleas on the cat, she did confirm seeing flea dirt. 10 Jun 2019: The owner saw 2 live fleas on the cat. The owner applied an additional dose of FRONTLINE PLUS. The owner reports the cat is an indoor/outdoor cat. The cat has been on FRONTLINE PLUS previously without any issue. No further medical information expected.

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						ok?: Yes					
09-Jun-2019	UAE; 19US032991; -; U.S.A	**Species:** Canine **Breed:** Boxer **Sex:** M **Sex qualifier:** - **Age:** 9.00 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?:** No (Treatment / vaccination program not respected)	08-Jun-2019	09-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 09 Jun 2019 an animal owner contacted Safety Call International (SCI) to report the following event in Teebone, a 9 year old, 45 pound, intact male Boxer. 05 Jun 2019*: Approximately 1/2 vial of FRONTLINE PLUS DOGS 45-88 LB (S62111AL) was applied to the canine. 08 Jun 2019: 1 tube of FRONTLINE PLUS was applied to the canine. 09 Jun 2019: The animal owner reports that the canine is urinating more, having accidents in the house, eating grass, and the eyes appear different. The canine has preexisting kidney disease and is on K/D kidney diet and subcutaneous fluids. No further information provided.
10-Jun-2019	UAE; 19US033003; CA; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 Month(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	10-Jun-2019	10-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 10 Jun 2019 the pet owner reported the following event for Forest a 9 month old, 10 pound, male neutered, Domestic Mediumhair (crossbreed) Feline. 10 Jun 2019: The pet owner applied 1 vial of FRONTLINE PLUS CATS (S40601AX) to the skin between the shoulder blades but it went more to one side then the center. About 30 minutes later the cat licked some of the product and the cat began drooling and foaming at the mouth. Minutes later the owner wiped the cats mouth and the cat seems to have recovered. No further medical information is expected.
10-Jun-2019	UAE; 19US033025; 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:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Apr-2019*	02-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 13 June 2019, the owner reported the following event for 2 canines (all other signalments unknown). Apr 2019*: The dogs started on FRONTLINE PLUS on a monthly basis. 1 June 2019*: The most recent vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown and product unsubstantiated) was applied between the shoulder blades, by the pet owner. 2 June 2019*: The dogs had a large amount of fleas. The dogs have not been bathed or gone swimming. The dogs do not have any skin issues. The owner is not seeing any flea activity in the home. No further medical information is expected.
10-Jun-2019	UAE; 19US033065; CT; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 73.0 lbs	4	4	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	31-May-2019*	01-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019, the animal owner reported the following event for four 73.0 pound* canines of otherwise unknown signalment. 31 May 2019*: They received FRONTLINE PLUS DOG 45-88 LBS (R62001AR) one dose per canine topically between the shoulders for the first time. The canines went swimming in the pond 60 minutes post application. 01 Jun 2019*: The owner noticed a small amount of fleas on the canines. The canines are experiencing pruritus and erythema. One of the canines does frequent a training facility. The owner noted fleas on the canines and off of the canines in the household

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						product used ok?: Yes					prior and post application. They have not presented to the veterinary clinic. No treatments have been initiated. Their current condition is ongoing. There are no other pets in the household. No further medical information expected.
10-Jun-2019	UAE; 19US033071; TN; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **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?:** Unknown to Company	16-Apr-2019	26-May-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019, the pet owner reported the following event for a 60 lb male canine, additional signalment details unknown. 16 Apr 2019: Dog began receiving doses of FRONTLINE PLUS DOG 45-88 LBS (S62202AX) (FL) topically in an unknown manner. 19 May 2019: Dog received his most recent dose of FL. Unknown date late May 2019: Pet owner began to find a lot of fleas on the dog. Pet owner also saw a lot of flea dirt. The pet owner stated that fleas are found in the home as well. The dog has free access to the outdoors and spends most of the day outside. There are 2 other dogs in the household that are treated with other products. No further medical information expected.
11-Jun-2019	UAE; 19US033075; -; U.S.A	**Species:** Canine **Breed:** Pekingese **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 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	10-Jun-2019	10-Jun-2019	0 Day(s)	D-C	Suspected Adverse Event: On 10 Jun 2019 an animal owner reported the following event in Angel, a 1 year old, 5 pound, male neutered, Pekingese Poodle mix. 10 Jun 2019: FRONTLINE PLUS (lot S61006AL) applied for the first time. Approximately 13 hours later, the pet experienced vomiting, difficulty breathing, and shivering. Bathed with Dawn dish soap. No further information provided nor expected.
10-Jun-2019	UAE; 19US033077; 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:** Advantage; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	08-Jun-2019*	10-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 June 2019, the owner reported the following event for 3 cats (signalment unknown). *8 June 2019: The cats had fleas and was scratching, one vial of FRONTLINE PLUS CATS (S41003AW) was applied to the skin between the shoulder blades for the first time. 9 June 2019: The fleas went away and the scratching decreased. 10 June 2019: The cats are covered with more fleas than before and they are scratching. The cats have been having an issue since early spring and they were on Advantage before the FL. The cats are strictly indoors and there are fleas in the home. There is one cat that has FAD. No further information available.
10-Jun-2019	UAE; 19US033083; MD; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 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 /	06-Jun-2019	10-Jun-2019	4 Day(s)	D-D	Suspected Adverse Event: On 10 Jun 2019, the owner reported the following event for Sweetie, a 15 pound, male neutered,3-4 year old*, Domestic Medium Hair. 6 Jun 2019: One vial of FRONTLINE PLUS CATS (R41118) was applied topically in between the pets' shoulder blades by the owner. 10 Jun 2019: The cat was lethargic and not acting normally. The cat is a part of a stray colony and was not presented to clinic. This is the first application for the cat.The cat's symptoms are on

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						Cutaneous **Was the product used ok?:** Yes					going.No further medical information expected.
10-Jun-2019	UAE; 19US033084; MN; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** - **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-May-2019	07-Jun-2019	4 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 11 June 2019, the owner reported the following event for Kirby, a 35 pound, medium mixed breed dog. 10 May 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (R60316AL) was applied to the skin between the shoulder blades. 7 June 2019: Kirby was diagnosed with Ehrlichiosis at the vet office and prescribed Doxycycline. Kirby is exposed to woods and grass, he has been on FL seasonally since 2018 and this was his first dose given this season. No further information.
10-Jun-2019	UAE; 19US033099; -; U.S.A	**Species:** Canine **Breed:** Pomeranian **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown dog shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	21-May-2019	09-Jun-2019	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019 a pet owner reported the following event for Gadget, a 10 pound male Pomeranian of unknown age and reproductive status. 21 May 2019: Owner applied 1 vial FRONTLINE PLUS DOGS 5-22 LBS (lot unknown) to skin between the shoulder blades. 23 May 2019: Dog was bathed at the groomer. 9 Jun 2019: Owner took dog for a walk in the neighborhood on the sidewalk and that evening found four fleas on the dog and removed them. There are no other pets in home and the dog rarely goes outside, as the dog goes potty in the home. The owner applied the product monthly for an unknown number of years until Mar 2019* when he applied the last dose until 21 May 2019 and has never seen fleas on the dog before. No further medical information expected.
10-Jun-2019	UAE; 19US033106; ME; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 6 lbs	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-2004*	01-Jan-2013*	9 Year(s)	D-A	Suspected Lack of Efficacy Claim: On 10 Jun 2019 the pet owner reported the following event via mail for Poe, a feline of unknown further signalment. Unknown date: Started on FRONTLINE PLUS CATS (product unsubstantiated) (lot and expiration unknown), unknown volume, route, application site, and frequency. Unknown date 2013: The feline was diagnosed with Lyme disease via an unknown test type. It is unknown if the feline was symptomatic at this time or what treatment was performed. Unknown date 2015: The feline was euthanized under unknown circumstances. The pet owner reported via mail a second feline has been diagnosed for Lyme disease while on FRONTLINE PLUS CATS (product unsubstantiated) (see case number 19US033122). No further information is available at this time. UPDATE 17 Jun 2019: Per phone call received from pet owner: Unknown Date 2013: The cat was lethargic, anorexic, and had trouble standing for approximately 1-2 days. Then the cat presented to the clinic and was diagnosed Lyme and Anaplasma positive via an uknown test. The cat was treated with doxycycline. The cat continued to lose weight over the next few years and ultimately was euthanized in Jul 2015. No further medical information expected.

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10-Jun-2019	UAE; 19US033122; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 16.3 lbs	2	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*	24-May-2019*	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jun 2019 the pet owner reported the following event via mail for a female feline of unknown further signalment. Unknown date 2015: Started on FRONTLINE PLUS CATS (product unsubstantiated) (lot and expiration unknown), unknown volume, route, application site, and frequency. 1 May 2015: The feline was diagnosed with Lyme disease via an unknown test type. It is unknown if the feline was symptomatic at this time or what treatment was performed. The pet owner reported via mail a second feline in the house hold that was diagnosed for Lyme disease and subsequently euthanized while on FRONTLINE PLUS CATS (product unsubstantiated) (see case number 19US033106). No further information is available at this time. UPDATE 17 Jun 2019: Per phone call received from pet owner: The cat's name is Jagger and is a 4 year old, 16.3 pound, spayed female Domestic Shorthair. 24 May 2019*: The pet owner woke up and did not see the cat in the bedroom which was unusual. She found the cat lying around downstairs and she did not want to move much and did not want to eat. The cat presented to the clinic and had a fever of 104.9 F. She tested positive for Lyme disease on a Snap 4 DX test and was treated with doxycycline, Cerenia, and Mirtazapine. No further medical information expected.
11-Jun-2019	UAE; 19US033149; MD; U.S.A	**Species:** Canine **Breed:** Spaniel (Cocker) **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 29 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-Apr-2019	30-Apr-2019*	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jun 2019, a pet owner reported the following event for Lexi, a 9 year old, 29 pound, spayed female Cocker Spaniel. 27 Mar 2019: The dog received 1 application of FRONTLINE PLUS DOGS 23-44 LBS (R61704AL) topically between the shoulder blades in one spot for the first time this year. A 6 pack was purchased from Costco on an unknown date. The pet owner did not notice fleas prior to the application. 27 Apr 2019: The dog received 1 application of FRONTLINE. 30 Apr 2019*: The pet owner noticed that the dog was scratching all over. No fleas were noted at this time. 24 May 2019: The dog was groomed. 27 May 2019: The dog received the most recent application of FRONTLINE. The pet owner stated that over the past few days, she has removed 5 live fleas from the dog. The dog gets groomed every 3 months. The yard is fenced in and there is a deck that the dog can crawl under. There are no other pets in the home. The pet owner stated that the dog has a history of being sensitive to fleas. The dog has been receiving FRONTLINE during the summer months starting in March since 2016* with no issues noted. The pet owner is concerned that this was a bad batch of FRONTLINE. No further medical information expected.
11-Jun-2019	UAE; 19US033155; NJ; U.S.A	**Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 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 /	01-Aug-2018*	02-Aug-2018*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jun 2019, the pet owner reported the following event for Kitty, a 8 year old, 14 pound, Mixed breed feline. 1 Jul 2018*: He received his monthly dose of FRONTLINE PLUS CATS(lot unknown). 1 Aug 2018*: He received his monthly dose of FRONTLINE PLUS CATS(lot unknown). 2 Aug 2019*: Fleas were beginning to be noticed on Kitty. 1 Sep 2018*: He received his monthly dose of FRONTLINE PLUS(R41206AW).

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						Cutaneous **Was the product used ok?:** Yes					2 Sep 2018*: The owner still noticed fleas, and noticed they were causing the animal to itch. The cat does frequent outside in the owner's yard. The owner stated she sprayed the yard and household with insecticide, and put down an unknown powder that is supposed to help with fleas. She stated she vacuums the house a lot and washes most things the cat uses frequently. No fleas have been seen in the home, or on anyone in the family. Kitty was bathed some times but owner would wait for animal to be dry before applying. The owner stated overall she is seeing about 1-5 fleas on the cat a day. Her current condition is recovered as of 1 Nov 2018, when the owner switched to Cheristin. There are no other animals in the household, but the owner did state there is a lot of wildlife and a few strays that pass through her wooded yard. No further medical information expected.
11-Jun-2019	UAE; 19US033161; -; U.S.A	**Species:** Feline **Breed:** Ragdoll **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 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 product used ok?:** Yes	10-Jun-2019	11-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 11 Jun 2019 an animal owner reported the following event in Rookie, an approximately 2 year old, approximately 12 pound, male neutered Ragdoll. 10 Jun 2019: FRONTLINE PLUS CATS (lot R41105AW) was applied between the shoulder blades. No fleas were seen at time of administration. 11 Jun 2019: The feline is reported to be jumping, rolling, and scratching at application site. The animal owner has rinsed the application site off with water. The feline has a history of receiving FRONTLINE PLUS CATS on unspecified dates without issues. No further information provided nor expected.
11-Jun-2019	UAE; 19US033162; MN; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 73 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-Jun-2019*	07-Jun-2019*	0 Day(s)	D-C	Suspected Adverse Event: On 11 Jun 2019 a clinic staff reported the following event for Cali, a 73 pound, 9 year old (1 Sep 2009), spayed female Labrador Retriever. 2016*: Dog was diagnosed with Lyme disease. 7 Jun 2019*: Owner applied FRONTLINE PLUS (unsubstantiated) (lot unknown) topically to the dog in an unknown location for the first time and within 2 days the dog developed a head tilt to the left, does not want to get up and move around or go up the stairs. The dog did not present to the clinic or received treatment. 9 Jun 2019*: The dog recovered without treatment. The owner also reported to the clinic that the dog had the same symptoms after NEXGARD administration in Jun 2019* and that is reported in case 19US033137. No further medical information expected. UPDATE 13 Jun 2019: The dog received FRONTLINE PLUS (unsubstantiated) (65331-5) (invalid lot). No further medical information expected.
11-Jun-2019	UAE; 19US033163; MN; U.S.A	**Species:** Canine **Breed:** Australian Cattle Dog **Sex:** M **Sex qualifier:** Neutered **Age:** 1.50 Year(s) **Weight:** 33 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown flea collar; **Route:** Topical / Cutaneous	28-May-2019*	28-May-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jun 2019, the pet owner reported the following issue for Ivan, a 33 pound, 1.5 year old, male neutered, Australian Cattle Dog mix. 28 May 2019*: The dog was having an issue with live ticks crawling on him while out for hikes in the woods. The owner purchased a 3 pack of FRONTLINE PLUS DOG 45-88 LBS (S61009AL). 1 vial was applied to the dog in one area between the shoulder blades. The owner has been seeing a large amount of live ticks on the dog every day since the application. The dog is also wearing 2 unknown generic brand flea collars. It is unknown if the owner removed live ticks on the dog.

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						Was the product used ok?: Yes					The dog goes out for potty breaks in the yard, and for hikes in the woods daily with the owner. The dog has not had a bath recently and has not history of skin issues. No further medical information is expected.
11-Jun-2019	UAE; 19US033225; VA; U.S.A	**Species:** Canine **Breed:** Dachshund **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 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	17-Apr-2019	06-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 11 Jun 2019 a pet owner reported the following event for Sassy, approximately 15 pound*, 5 year old, spayed female Longhaired Dachshund. 17 Apr 2019, 17 May 2019, and 10 Jun 2019: Owner applied FRONTLINE PLUS DOG 5-22 LBS (S63009AL) to the skin between the shoulder blade. 6 May 2019*: Owner saw fleas on dog, 4 to 5 fleas a day. Owner gave a bath this day with an unknown shampoo. There is one other pet in the home, a cat, which is inside only, and had FRONTLINE applied the same days as Sassy. The cat does not have fleas. The two humans in the home have had 1 to 2 fleas jump onto them and the owner reports the fleas are very bad under his bed where the dog likes to lay. Owner has been using FRONTLINE on Sassy for approximately 4 years and has not had a flea problem previously. The owner sprays the house and the yard for bugs in the spring. Sassy does not go outside and goes potty in a litter box inside. No further medical information expected.
11-Jun-2019	UAE; 19US033226; CT; 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	28-May-2019	11-Jun-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 11 jun 2019, animal owner reported the following event in 2 unknown dogs. *28 Jan 2019: Started monthly FRONTLINE PLUS DOG 45-88 LBS (lot unknown) topically between the shoulder blades on both dogs with an unknown purchase history. 28 May 2019: A dose was applied. 11 Jun 2019: The pet owner found one live tick attached on each dog. The tick was removed. The pet owner thinks it was a deer tick but the species has not been identified. The pet owners have found ticks on them as well. The environment has not been treated and the dogs are indoor mostly. No further information expected.
11-Jun-2019	UAE; 19US033257; -; U.S.A	**Species:** Canine **Breed:** Cockapoo **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 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?:** No (Overdose)	28-May-2019	05-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 11 Jun 2019 an animal owner reported the following event in Reese, a 3 year old, 22 pound, Cockapoo. 28 May 2019: FRONTLINE PLUS 23-44 LBS (R62420AL) was applied to the canine. 05 Jun 2019: The animal owner saw 1 tick crawling on the canine's fur and an engorged tick on the canine. The canine is reported to receive FRONTLINE PLUS monthly and year round. The animal owner states that ticks have been found on the canine post FRONTLINE PLUS administration in Apr 2018 and May 2018 as well. No further information provided nor expected.
11-Jun-2019	UAE; 19US033261; GA; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** Neutered	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	09-Jun-2019	10-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 11 Jun 2019, a pet owner reported the following event for Collin, an 86 pound, 10 year old, neutered male, German Shepherd. 9 Jun 2019: The owner applied for the first time FRONTLINE PLUS DOG 45-88 LBS (S62204RX) with 1 dose applied topically between the shoulder blades. There are a total of 2 other dogs in

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		Age: 10.00 Year(s) **Weight:** 86 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					the home that are on the same size of FRONTLINE PLUS. The owner applies the product seasonally not year round. The owner is not seeing fleas on the other dogs only on Collin.The pet owner was not seeing fleas on her dog prior to applying the product. 10 Jun 2019: The pet owner saw more than 15 fleas on her dog. Her dog has access to a wooded backyard that is 1/4 of an acre and is heavily shaded. The dog spends the majority of the time in the yard with the housemates. The owner is not seeing fleas inside her home only on the dog. No further medical information expected as the owner refused to give additional details.
11-Jun-2019	UAE; 19US033267; MO; 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?:** Unknown to Company	01-Jun-2019*	02-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 11 June 2019, the owner reported the following event for a 3 canines (all other signalments unknown). 1 June 2019*: One vial of FRONTLINE PLUS DOG 5-252 LBS (lot unknown) was applied between the shoulder blades, by the pet owner. 2 June 2019*: The dogs had fleas. The dogs were bathed with dawn and a flea/tick shampoo on a unknown date. The owner is not seeing any flea activity in the home. The pet owner treated the back yard with unknown treatment. The pet owner also washes the bedding every 5 days. 10 June 2019: The most recent vial of the FRONTLINE PLUS was applied to the dog. It is unknown if fleas were seen before application of the product. No further medical information is expected. UPDATE 3 JUL 2019: Corrected was product used correctly to unknown.
11-Jun-2019	UAE; 19US033292; SC; U.S.A	**Species:** Feline **Breed:** Maine Coon Cat **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 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?:** Yes	04-May-2019	05-May-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jun 2019, the owner reported the following event for Willow, 2 year, 6 pound, spayed female, Maine Coon Feline. 4 May 2019: No fleas were found on the pet. One vial of FRONTLINE PLUS CATS (S40815BW) was applied between the shoulder blades for the very first time. 5 May 2019'*: The owner found 1 flea on the cat. No fleas were noted in the household. The owner bathed the cat in Dawn. 11 Jun 2019: The owner has continued to find sporadic fleas on the cat. The cat is strictly indoor. There is a dog in the household receiving NEXGARD and experiecning an issue (see case 19US033289). No further medical information is expected.
11-Jun-2019	UAE; 19US033314; CT; U.S.A	**Species:** Canine **Breed:** Shetland Sheep Dog (Sheltie) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 130 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?:** No (Low dose)	10-Jun-2019	11-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: 11 Jun 2019: An owner reported the following event in Cali; a 5 year old, 130 pound, spayed, female, Shetland Sheepdog. 10 Jun 2019: The owner administered one vial of FRONTLINE PLUS DOGS 23-44 LBS (lot unknown, package unavailable) between the shoulder blades, in a low dose off label manner. 11 Jun 2019: The dog exhibited yellow diarrhea. The owner confirms the dog could not lick the application site. The dog received the product in 2018 with no reactions. There is one other dog in the home who received the product with no reaction. UPDATE: 17 Jun 2019: The owner reports the dog is improving but still has soft stools. No further information available. UPDATE: 24 Jun 2019: Multiple attempts were made to obtain further medical information without success. No further medical information 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
11-Jun-2019	UAE; 19US033354; OK; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 38 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*	09-Jun-2019*	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jun 2019, a veterinarian reported the following event for Lucky, a 5 year old, 38 pound, neutered male Australian Shepherd mix. Unknown Date: The dog received 1 application of FRONTLINE PLUS DOG 23-44 LBS (Lot and Expiration Unknown) topically between the shoulder blades. 9 Jun 2019: The pet owner noticed scabs on the dog's head and found an unknown amount of live fleas on the dog. The dog went to the groomer and another dose of FRONTLINE was applied. It is unknown if fleas were seen prior to application. 11 Jun 2019: The dog presented to the clinic for a new patient exam and the veterinarian wanted to know if the dog could receive NEXGARD since the owner felt like the FRONTLINE was not working. The pet owner was still seeing an unknown amount of live fleas and the dog seemed uncomfortable. It is unknown what environment this pet is exposed to and unknown if the dog has been on FRONTLINE before. This is the extent of information known.
11-Jun-2019	UAE; 19US033367; CA; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 6.000 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	01-May-2019*	04-May-2019*	3 Day(s)	D-D	Suspected Adverse Event: On 11 Jun 2019, a pet owner reported the following event for Conner, an approximately 8 year old, 6* pound, neutered male Maltese. 2011*: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (S61203AX) topically between the shoulder blades in one spot. Unknown Date: The dog received 1 application and an unknown amount of days later, the dog's skin turned black where the product was applied. The pet owner was not able to give an exact time of when the skin turned black. Unknown Date: The owner discontinued the FRONTLINE and the black spot on the skin cleared up. Unknown Date: The owner started using FRONTLINE again but applied it after the dog had received a bath and was still wet. The black spot did not occur again. The owner stated that she has been applying the FRONTLINE after the dog gets bathed and is still wet for an unknown amount of time. This is the extent of information known.
11-Jun-2019	UAE; 19US033405; 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 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Jun-2019	11-Jun-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 June 2019, the owner reported the following event for a cat (signalment unknown). 2 June 2019: One vial of FRONTLINE PLUS CATS (lot unknown) was topically applied to the skin between the shoulder blades. 11 June 2019: The owner noticed the cat was full of flea dirt without any visible fleas. The cat is treated monthly yearround. No further information available.
11-Jun-2019	UAE; 19US033406; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	21-May-2019	22-May-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jun 2019, the owner reported the following event for An approx. 7 year old, 12 pound female canine (all other signalments unknown). 2012*: Started on monthly doses of FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown) topically by the owner. 21 May 2019: Most recent dose of FRONTLINE was applied.

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		Age: 7.00 Year(s) **Weight:** 12 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					22 May 2019*: The owner started seeing fleas on the dog. The owner is not seeing fleas in the home. The dog goes for walks in the neighborhood and in the park where there are bushes and trees. There is another dog in the home also treated with FRONTLINE and is not having any problems. No further medical information expected OR No further information available at this time. UPDATE 3 Jul 2019: After an internal call review, the last date of application was on 11 June 2019. No further medical information expected.
11-Jun-2019	UAE; 19US033448; CA; U.S.A	**Species:** Canine **Breed:** Pomeranian **Sex:** U **Sex qualifier:** Unknown **Age:** - **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	11-Jan-2019	11-Jan-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 June 2019, the owner reported the following event for a 10 pound Pomeranian. * Jan 2019: The dog had fleas and one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied to the skin between the shoulder blades. The fleas went away for 20 days and then returned. The dog is exposed to a small grass area of an apartment complex for potty breaks. The dog is treated monthly year round and the owner explained the fleas always leave for the first 20-25 days and then comes back. Dog has been on FL for at least a year. There are no other dogs in the home. No further information available.
12-Jun-2019	UAE; 19US033453; NJ; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 68 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Galliprant; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Indication not indicated / recommended)	01-Jun-2009*	03-Jun-2019	2 Day(s)	D-C	Suspected Lack of Efficacy Claim: On 12 Jun 2019 a pet owner reported the following event for Bayley, a 68 pound, 11 year old, spayed female Labrador Retriever. 2009*: Dog started receiving FRONTLINE PLUS DOGS 45-88 LBS (lot unknown) monthly. 3 Jun 2019: Dog presented to the clinic for a routine annual visit and tested Lyme disease positive on an unknown test with a result of > 300 (units unknown) and was treated with an unknown antibiotic. The owner has never seen ticks on the dog. The previous testing history is unknown. The owner reports decreased muscle mass bilateral rear limbs for an unknown duration, which he attributed to osteoarthritis, which the dog receives Galliprant for. There is one other dog in the home who received FRONTLINE PLUS and tested Lyme disease negative. No further medical information expected.
12-Jun-2019	UAE; 19US033512; NJ; U.S.A	**Species:** Canine **Breed:** Samoyed **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 57 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** AFOXOLANER 68 MG CHEWABLE TABLETS; **Route:** unknown **Was the product used ok?:** No	01-Sep-2018*	09-Jun-2019	8 Day(s)	D-C	Suspected Lack of Efficacy Claim: On 12 Jun 2019, the veterinarian reported the following event for Cooper, a 6 year old (born 13 Apr 2013) 57 pound male neutered Samoyed. Feb 2018*: The dog was started on NEXGARD (68 mg) (lot and expiration unknown) with an 8 pack purchased. 27 Jul 2018: The dog had a negative 4Dx test. Sept 2018*: The pet owner started the dog on FRONTLINE PLUS DOG (unsubstantiated) (lot unknown) with an unknown purchase history. 9 Jun 2019: The dog was not eating. 11 Jun 2019: The dog presented the clinic with a temperature of 105F. A CBC/Chemistry was performed with the abnormal result as follows: PLT 82,000 (175,000-500,000). Abdominal/thoracic radiographs and a 4Dx were WNL. The results from a UA and a tick borne disease PCR are not back. Rickettsial organisms were seen on a pathology review of the CBC. The clinic treated with Doxycycline, Dexamethasone, SC fluids, and Cerenia.

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						(Indication not indicated / recommended)					The dog's status was the same at the time of the phone call. No further medical information expected.
12-Jun-2019	UAE; 19US033549; OH; 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	10-Jun-2019*	12-Jun-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 Jun 2019 the pet owner reported the following event for two felines of unknown signalment. 10 May 2019*: The pet owner applied FRONTLINE PLUS CATS (lot unknown), 1 dose, topically, unknown application site for the first time. It is unknown if there were fleas on the felines prior to application. 10 Jun 2019*: The most recent dose was applied topically to an unknown application site on both felines. Currently, the pet owner reports seeing a large amount of fleas on both felines who spend all of their time inside the home. There is one canine in the home that is also exhibiting fleas (see case number 19US033538). No further medical information is expected.
12-Jun-2019	UAE; 19US033557; TX; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Chocolate) **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?:** Yes	06-Mar-2019*	07-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 June 2019, the owner reported the following event for a male, Retriever (Labrador, Chocolate) (all other signalments unknown). Unknown date: The pet owner stated that dog has been on FRONTLINE PLUS for an unknown amount of years on a monthly basis year round. 6 June 2019: The most recent vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades, by the pet owner. 7 June 2019*: The dog had 1 flea. The dog does not get bathed. The dog does not have any skin issues. The owner is not seeing any flea activity in the home. The pet owner stated that she has treated the outside environment with an unknown treatment on 8 June 2019. No further medical information is expected.
12-Jun-2019	UAE; 19US033558; MI; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Capstar; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	13-May-2019	14-May-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 Jun 2019, the pet owner reported the following event for 3 cats, Rusty, Tipper, and Oreo, all males neutered, 13 years old, Feline mixed/ various breeds, other signalment unknown. 6 May 2019: The cats received Capstar. 13 May 2019*: The pet owner first noticed 15+ fleas on the cats. The pet owner applied one dose of FRONTLINE PLUS CATS (lot number unknown) topically to skin between the shoulder blades of the cats on monthly basis year round since May of 2018. 14 May 2019: The pet owner continued to see 15+ fleas on the cats. 12 Jun 2019: The cats were in good health at time of application. The cats were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen fleas in the home jumping and biting. The cats have no history of skin problems or any other issues with topical treatments. The cats have had flea problem before in the past and it resolved. The cats share home with 3 dogs that have no issue with fleas and are treated with unknown amount of NEXGARD (lot number unknown , expiration number unknown)(product unsubstantiated). The cats have not received any other topical treatments. The cats have not been bathed. The cats are indoors and outside. The current status of the cats are unknown. No further medical information.

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12-Jun-2019	UAE; 19US033565; WI; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 54 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** RECOMBITEK LYME - 2126.R0; Zoetis Lyme; AFOXOLANER 68 MG CHEWABLE TABLETS; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Indication not indicated / recommended)	19-Apr-2017*	12-Jun-2019	12 Month(s)	D-C	Suspected Lack of Efficacy Claim: On 12 Jun 2019, the vet reported the following event for Flint, a 54 pound, 2 year old (born 10 Jan 2017), neutered male Golden Retriever. Flint was vaccinated with a Zoetis Lyme on 19 Apr 2017 and 18 May 2017 via unknown route and location. Apr-May 2017*: Flint tested faint Lyme positive via a 4DX test. A Quant C6 was performed with a value of 70. The vet recommended additional testing and treatment, but the owner declined. 13 Jun 2018: Flint was vaccinated with RECOMBITEK LYME (Lot and Expiration Unknown) via unknown route and location. 12 Jun 2019: Flint tested Lyme positive via a routine 4DX. The vet plans to submit samples for a Cornell MultiPlex. The pet is currently asymptomatic. Flint is also on NEXGARD (product unsubstantiated)(Lot and Expiration Unknown) with the following purchase history: 1 chew on 19 Apr 2017, 4 chews on 18 May 2017, 7 chews on 13 Jun 2018, and 7 chews on 12 Jun 2019. No further information at this time. UPDATE 12 Jun 2019: Per veterinarian, the pet also received RECOMBITEK LYME on 12 Jun 2019. No further medical information at this time. UPDATE 17 Jun 2019 per medical record received on 14 Jun 2019: Multiplex results: OSPA pos 3635 (>1500-30,000), OSPC pos 2821 (>1000-22,000), OSPF pos 15,964 (>1500-30,000). No further medical information at this time. UPDATE 19 Jun 2019 per medical record received on 18 Jun 2019: 13 Jun 2018: Flint was vaccinated with RECOMBITEK LYME (42222, 21 Sep 2019) via unknown route and location and also tested faint Lyme positive via a 4DX test. Flint also started NEXGARD (product unsubstantiated)(Lot and Expiration Unknown) on 13 Jun 2018. Flint previously received FRONTLINE PLUS (product unsubstantiated). 29 Jun 2018: A Quant C6 was performed with a value of 70. 12 Jun 2019: Flint was vaccinated with RECOMBITEK LYME (42239, 24 Jan 2021) via unknown route and location. 18 Jun 2019: The pet was treated with doxycycline, and a urine protein creatinine ratio is
12-Jun-2019	UAE; 19US033566; -; 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?:** No (Route not indicated / recommended)	09-Jun-2019*	10-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 June 2019, the owner reported the following even for 2 cats (signalment unknown). *9 June 2019:The cats were scratching (no fleas seen) and one vial of FRONTLINE PLUS CATS (FL) (S0606AW) was topically applied to the skin and fur on the neck. *Unknown date: The owner noticed a few fleas on each cat. The cats are strictly indoor but have access to screens throughout the home and are allowed to sit in open windows. The home is also treated and there are no fleas inside the home. The cats are treated 1-2 times a year as needed (length of time on FL is unknown). It is unknown if the cats have any skin issues and how often they are bathed. No further information available.
12-Jun-2019	UAE; 19US033627; MA; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various	2	2	0	**Product used:** FIPRONIL 10%/S	22-May-2019*	23-May-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 12 Jun 2019, the pet owner reported the following event for 2 dogs, Max, male neutered, 20 pounds, 7 years old, Mixed breeds/ various breeds. The pet owner

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		Sex: X **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 12 - 20 lbs				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					also reported the following event for Molly a female spayed, 7 year old, 12 pound, mixed breed/various. 1 May 2019*: The pet owner first noticed 15+ fleas on the dogs. 22 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (lot number unknown) topically to skin between the shoulder blades of the dogs on monthly basis year round. 23 May 2019: The pet owner continued to see 15+ fleas on the dogs. 8 Jun 2019*: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS topically to skin between the shoulder blades of the dogs on monthly basis year round. The dogs were in good health at time of application. The dogs were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen fleas in the home jumping and biting her. The dogs have no history of skin problems or any other issues with topical treatments. The dogs have not had flea problem before in the past. The dogs have not received any other medications or topical treatments. The dogs are indoors and outside in fenced yard. The current status of the dogs are unknown. No further medical information.
12-Jun-2019	UAE; 19US033632; NY; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 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	06-Jun-2019*	07-Jun-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 12 June 2019, the owner reported the following event for Sugar, a 6 year old, 60 pound, spayed female Retriever Golden. *6 June 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (FL) (S62408AX) was topically applied to the skin between the shoulder blades. *7 June 2019: The dog developed soft stool. The soft stool is still ongoing and the dog has not been seen by the vet. The dog has had FL in the past without issue. No further information available.
12-Jun-2019	UAE; 19US033645; CA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 6 - 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	19-Mar-2019	20-Mar-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 12 Jun 2019 the pet owner reported the following event for 2 unknown 6-18 pound felines. All other signalments are unknown. 19 Mar 2019: The owner applied 1 vial of FRONTLINE PLUS CATS (S40603) to the skin between the shoulder blades for the first time. The owner was noticing fleas periodically prior to application. 20 Mar 2019: The owner started noticing 1 flea and lots of flea dirt on the cats each day. *Apr 2019: The owner fogged the house with an unknown fogger on an unknown date with no change in the amount of fleas on the cats. 23 Apr 2019: The owner applied another dose. 14 May 2019: The owner applied another dose. 1 Jun 2019: The owner applied the most recent dose. 2 Jun 2019: The owner noticed 1 flea per day and lots of flea dirt on the cats each day. There are no other pets in the home. The cats are indoor only cats. There is no indoor flea activity present inside the home. No further medical information expected.
12-Jun-2019	UAE; 19US033666;	**Species:** Canine **Breed:** Retriever	1	1	0	**Product used:** FIPRONIL	09-Jun-2019	12-Jun-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 Jun 2019 an animal owner reported the following event in Carson, a 4 year old, 100

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	-; U.S.A	Labrador **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 100 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					pound, male neutered Labrador Retriever. 09 May 2019: FRONTLINE PLUS DOG 89-132 LB (S61017AL) was administered in between the shoulder blades. No fleas at time of administration. 09 Jun 2019: FRONTLINE PLUS administered. 12 Jun 2019: The animal owner reported seeing 6 live slow moving fleas on the canine. There is 1 other dog in the household that is treated with FRONTLINE PLUS. The canine has access to the outdoors. There are rabbits, raccoons, squirrels, and chipmunks in the area. No further information provided nor expected.
12-Jun-2019	UAE; 19US033677; MO; 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	09-Jun-2019	10-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 12 Jun 2019, Animal owner reported the following event for her 2 cats. 09 Jun 2019: The pet owner applied the entire contents of 1 vial of FRONTLINE PLUS CATS (Lot: P40203B) topically between the shoulder blades for the first time. 10 Jun 2019: The cats started vomiting after eating. 11 Jun 2019: The cats stopped eating. 12 Jun 2019: The symptoms are still ongoing. The cats have not groomed eachother and the pet owner stated she didnt think that got into anything toxic. There has not been veterinary intervention. No further information expected.
12-Jun-2019	UAE; 19US033702; VA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 19.00 Year(s) **Weight:** 12 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Capstar; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-May-2019	05-Jun-2019*	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 Jun 2019, the pet owner reported the following event for Lamont, a 12 pound, 19 year old, male neutered, Domestic Longhair (Crossbreed). Mar 2019:The cat was not having an issue with fleas. 1 vial of FRONTLINE PLUS CATS (S40117AW) was applied to the cat in one area between the shoulder blades for the first time of the season. 25 May 2019: 1 vial was applied to the cat. 5 Jun 2019*: The owner noticed a large amount of fleas on the cat. The owner gave the cat a capstar pill to kill the fleas. The owner treats seasonally since 2018. The cat is indoor/outdoor, and spends a lot of time on the deck in the back yard and in the garage. There are no fleas present in the home. The cat has no history of skin issues and has not had a bath recently. The cat is mobile. No further medical information is expected.
12-Jun-2019	UAE; 19US033714; VA; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 6 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	02-Jun-2019	02-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event and Suspected Lack of Efficacy Claim: On 12 Jun 2019, the pet owner reported the following event for Lilly, a 1 year old 6 pound* female spayed Domestic Mediumhair. 2 Jun 2019: The cat was applied a dose of FRONTLINE PLUS CATS (F41307AW) for the first time down to the skin between the shoulder blades for fleas. Almost immediately after, the cat was stumbling, hacking, blinking, and hide for a few hours and then recovered. The cat was also scratching at the application site, so it may have licked its foot. 12 Jun 2019: The cat still had a large amount of fleas. There is another cat and dog in the home who were also given a dose of FRONTLINE on the same day. The pets were not on any kind of flea treatment before this dose. No further medical information expected.
12-Jun-2019	UAE; 19US033715;	**Species:** Canine **Breed:** Pekingese	1	1	0	**Product used:** FIPRONIL	05-Jun-2019	05-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 12 Jun 2019 the pet owner reported the following event for Angel a 4 year old, 10 pound, intact female

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	OH; U.S.A	**Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 10 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					Pekingese. *2015: The owner began applying 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) to the skin between the shoulder blades and repeated on a monthly and year round basis thereafter. 5 Jun 2019: The most recent dose was applied. This was the first dose of this lot. Hours after applying the product the owner noticed the dog began scratching at her side and legs. The owner is not seeing any fleas on her. The symptoms are ongoing and the dog has not presented to the vet clinic. The dog is mainly an indoor only dog. No further medical information expected.
12-Jun-2019	UAE; 19US033757; NC; U.S.A	**Species:** Feline **Breed:** Persian, Tortoiseshell **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 3.1 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	06-Jun-2019	10-Jun-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 12 Jun 2019, the pet owner reported the following event for Freya a female intact, 3.1 pound, 3 month old, Persian, Tortoiseshell. 6 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S41006AW) topically to skin between the shoulder blades of Freya for the first time. 10 Jun 2019*: After approximately 4 days post application the pet owner noticed Freya experience vomiting up to 3 times a day. Freya was in good health at time of application. Freya was not presented to veterinarian. Freya has not had any other products at the same time as the FRONTLINE PLUS CATS application. Freya does not have history of drug or vaccine reactions.Freya has not had FRONTLINE prior to reaction. Freya is currently at home with ongoing issue. No further medical information.
12-Jun-2019	UAE; 19US033758; WI; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 79 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-May-2019	12-Jun-2019	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 Jun 2019 the pet owner reported the following event for Jackie Brown a 10 year old, 79 pound female spayed Retriever (Labrador, Black) mix. *2009: The owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S62111AL) to the skin between the shoulder blades for the first time and repeated it on a monthly and year round basis. 20 May 2019: The owner applied the most recent dose. 12 Jun 2019: The owner has found 3 ticks on the dog at separate times. 1 tick was attached, engorged and dead. A second tick was attached, not engorged and alive. The third tick was attached, engorged and alive. All of the ticks have been on the dog's chest area and the owner removed them. All ticks were seen at seperate times since last application with the most recent on 12 JUN 2019. There are no other pets in the home. The dog has access to long grass, trees and woods. The owner takes the dog hiking frequently. No further medical information expected.
12-Jun-2019	UAE; 19US033774; LA; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 12 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	19-Feb-2019	07-Jun-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 June 2019, the owner reported the following event for a 12 pound, female Maltese/Poodle mix. 18 Feb 2019: The dog received a Dawn bath. 19 Feb 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (R61418AL) topically to the skin between the shoulder blades for the first time. 1 March 2019: The owner found 15 fleas on the dog and bathed her with Dawn. 5 March 2019: The dog was bathed with Dawn soap. 14 March 2019: The dog had 14 fleas. 23 March 2019: The second application was given per label. The fleas went away for 3 days. 10 April 2019 and 12 April 2019: The dog had fleas and was bathed in Dawn.

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											17 April 2019: The dog went to the groomer and had fleas. 19 April 2019 and 21 April 2019: Another application was given per label. 8 May 2019: The dog received a Dawn bath. 21 May 2019: The most recent application was given per label. 27 May 2019: The dog had 10-15 fleas and was bathe with Dawn. 7 June 2019: The dog had 16 fleas and was bath with Dawn. The dog lives in the country and is exposed to grass daily. The dog is bathed with Dawn every time fleas are noticed. There is one outdoor cat that is not treated. No further information available.
12-Jun-2019	UAE; 19US033775; TX; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 110 lbs	-	-	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-Jun-2019	10-Jun-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 Jun 2019, the owner reported the following event for 2 canines, weighing 46- 110 pounds all other signalment unknown. 5 Jun 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (P61601AR) was applied topically in between the pet's shoulder blades per the label instructions by the owner. 10 Jun 2019: A moderate- large amount of ticks were seen on the pets. The dogs are outdoor only and access to a fenced in yard. Skunks and Possums are noticed in the area. This is the first treatment of FRONTLINE PLUS and ticks were seen prior to treatment. The owner presented the dogs to the clinic and was prescribed Bravecto. 11 Jun 2019: The dog recovered. No ticks have been seen on the dogs. There is another pet within the home see addtional case 19US037242.No further medical information expected.
12-Jun-2019	UAE; 19US033778; TX; U.S.A	**Species:** Canine **Breed:** Beagle **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 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	08-Jun-2019	12-Jun-2019	4 Day(s)	D-C	Suspected Adverse Event: On 12 Jun 2019, the pet owner reported the following event for Rosy a female spayed, 24 pound, 2 year old, Beagle. Unknown dates: Rosy has had FRONTLINE PLUS DOG previously. 8 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 23-44 LBS (S61009AL) topically to skin between the shoulder blades of Rosy for the first time this year. 12 Jun 2019: Pet owner noticed Rosy with open wound and chemical burn at application site. Rosy was not presented to veterinarian but did see animal eye doctor and was given Neomycin cream. Rosy was in good health at time of application. Rosy has not had any other products at the same time as the FRONTLINE PLUS CATS application. Rosy does not have history of drug or vaccine reactions. Rosy is currently at home with ongoing issue. No further medical information. 1 Jul 2019: PER THE OWNER The dog is recovered. No further medical information expected.
12-Jun-2019	UAE; 19US033782; NJ; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 5.5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL 9.8% / S-METHOPRENE 8.8% / PYRIPROXYFE	01-Jun-2019*	11-Jun-2019	10 Day(s)	D-C	Suspected Adverse Event: On 12 Jun 2019, the pet owner reported the following event for Max a male neutered, 5.5 pound, 12 year old, Yorkshire Terrier. Unknown date: The pet owner has used FRONTLINE PLUS 5-22 LBS (lot number unknown)(Product unsubstantiated) previously. 9 Jun 2019: The pet owner applied one dose of FRONTLINE GOLD DOG 5-22 LBS (PP27481) topically to skin between the shoulder blades of Max for the first time. 11 Jun 2019: The pet owner noticed Max shaking. 12 Jun 2019: Max has recovered. Max was in good health at time of application. Maxi was not

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						N 0.25% TOPICAL SOLUTION; **Route:** unknown **Was the product used ok?:** Unknown to Company					presented to veterinarian. Max has not had any other products at the same time as the FRONTLINE GOLD DOG 5-22 LBS application. Max does not have history of drug or vaccine reactions. Max has had FRONTLINE prior to reaction. No further medical information.
13-Jun-2019	UAE; 19US033785; NY; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **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	07-May-2019	13-Jun-2019	5 Week(s) 2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 13 Jun 2019, a pet owner reported the following event for 6 felines of unknown signalment. 7 Mar 2019: The owner started all 6 cats of FRONTLINE PLUS CATS (lot unkonwn) by applying 1 dose topically between the shoulder blades. 7 Apr 2019 and 7 May 2019: The owner applied 1 vial of FRONTLINE PLUS CATS (lot unkonwn) topically between the shoulder blades to all 6 cats. 13 Jun 2019: The owner is seeing fleas. Four of the cats and indoor/outdoor and the other 2 are indoor only. The cats were previously on Advantage for 20+ years. The owner is spraying the house and treating the oustide. The owner has been treating year round. No further medical information expected.
13-Jun-2019	UAE; 19US033802; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 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	11-Jun-2019	13-Jun-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 13 Jun 2019, Animal owner reported the following event for Bob, an 8 year old, spayed female domestic shorthair feline. 22 May 2019: The patient ran away. 06 Jun 2019: The pet owner had the environment treated for fleas, ticks and other seasonal insects. 11 Jun 2019: The cat returned and the pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (Lot unknown) topically between the shoulder blades. The pet owner noted she did not see any fleas prior to applying the product. 13 Jun 2019: The pet owner is seeing live fleas on the cat. There are no other animals in the home. The cat is being housed in the garage. No further information expected.
13-Jun-2019	UAE; 19US033808; MI; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 64 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 (Treatment / vaccination program not respected)	22-May-2018*	23-May-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim:On 13 June 2019, the owner reported the following event for Tomaka, 3 years old, 64 pounds, spayed female, Large crossbred (>20 kg). 2018*: The dog started using the FRONTLINE PLUS on a monthly basis year round. 22 May 2019: The recent vial of FRONTLINE PLUS DOG 45-88 LBS (S60211AR) was applied between the shoulder blades, by the pet owner. 23 May 2019: The dog had a wood tick. The pet owner removed the tick. The pet owner stated that she has seen 1 tick a day since application on the product. The dog does not get bathed. The owner is not seeing any tick activity in the home. There are 2 other dogs in the home sharing the FRONTLINE PLUS and is not currently having an issue with fleas. No further medical information is expected.
12-Jun-2019	UAE; 19US033840;	**Species:** Canine **Breed:** Retriever	1	1	0	**Product used:** FIPRONIL	05-May-2019	05-Jun-2019*	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 Jun 2019, the pet owner reported the following event through Safety Call International (SCI)

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	MO; U.S.A	(Golden) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 105 lbs				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)					for Payton, a 105 pound, 3 year old (12 Jun 2015), neutered male Golden Retriever. 05 May 2019: The pet owner administered a dose of FRONTLINE PLUS FOR DOGS 89-132 LBS (R60706AR). 05 Jun 2019*: Multiple ticks were found at dog while being boarded. 09 Jun 2019: The pet owner administered a dose of FRONTLINE PLUS FOR DOGS 89-132 LBS (R60706AR). 12 Jun 2019: There are fleas all over the dog. FRONTLINE PLUS was purchased at Sam's Club. Owner is wondering if she came across a bad batch of product. There are also 3 cats in the household that are all being treated with FRONTLINE PLUS (product unsubstantiated) (lot unknown). No further medical information. UPDATE 14 Jun 2019: The dog still has fleas and the cats do not. The pet owner does not apply year round. No further medical information expected.
13-Jun-2019	UAE; 19US033888; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	6	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?:** Unknown to Company	08-Jun-2019*	13-Jun-2019	5 Day(s)	D-D	Suspected Adverse Event: 13 Jun 2019: An owner reported the following event in 4 dogs of unknown signalment. 08 Jun 2019*: The owner administered one tube FRONTLINE PLUS DOG *product unsubstantiated, package was thrown away (lot unknown, package unavailable) in an unknown manner to 6 dogs. Ticks were seen at the time of application. 13 Jun 2019: 4 dogs are itching non stop. No fleas or ticks were seen. All dogs have received the product before and itched at the time of application with no fleas seen. No further medical information available.
13-Jun-2019	UAE; 19US033941; TX; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 55 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-Jan-2019	17-Jan-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 13 June 2019, the owner reported the following event for Barney, a 4 year old, 55 pound, neutered male Large mix breed dog. 16 Jan 2019: The dog has fleas and one vial of FRONTLINE PLUS 45-88 LBS (lot unknown) was topically applied to the skin between the shoulder blades. The dog is treated with FL monthly and has been having an ongoing flea issue for months. The dog is exposed to a fenced in grass yard for potty breaks. The dog is picking up a few fleas each day that the owner is flea combing off. It is unknown how often the dog is bath or have any skin issues. There are 2 treated indoor cats in the home who also have fleas, see case 19US033957. No further information available.
13-Jun-2019	UAE; 19US033951; MI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **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:** PO-Oral **Was the product used**	06-Jun-2019	12-Jun-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 13 Jun 2019, the pet owner reported the following event for a 72 pound, canine. All other signalments unknown. 6 Jun 2019: 1 vial of FRONTLINE PLUS 45-88 LBS (R62301AR) was applied to the dog in one area between the shoulder blades. 12 Jun 2019: The owner found 1 tick on the dog and removed it. The dog goes out for potty breaks and recreation. Owner has been treating year round for unknown number of years. Pet owner declined to complete the report. No further medical information is expected.

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						ok?: Yes					
13-Jun-2019	UAE; 19US033953; -; 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	30-May-2019*	13-Jun-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 13 Jun 2019, Animal owner reported the following event in 2 dogs. *30 May 2019: The pet owner applied the entire contents of 1 vial of FRONTLINE PLUS DOG 5-22 LBS (Lot unknown) topically between the shoulder blades for the first time. 13 Jun 2019: The pet owner noted seeing fleas. All additional information not obtained due to the pet owner declined reporting. No further information expected.
13-Jun-2019	UAE; 19US033957; TX; U.S.A	**Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** X **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 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	16-Jan-2019	17-Jan-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 13 June 2019, the owner reported the following event for a 4 year old domestic shorthair neutered male cat, and a 6 year old spayed domestic longhair. 16 Jan 2019: The cats had fleas and one vial of FRONTLINE PLUS CATS (S41004AW) was topically applied to the skin between the shoulder blades to each cat. The cats are treated with FL monthly and has been having an ongoing flea issue for months. Thecats are stictly indoors and picking up a few fleas each day that the owner is flea combing off. It is unknown how often the cats are bath or have any skin issues. There is one treated dog in the home who also have fleas, see case 19US033941. No further information available.
13-Jun-2019	UAE; 19US033965; OH; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **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	12-May-2019	01-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: 13 Jun 2019: An owner reported the following event in 4 unknown cats of unknown signalment that are indoor/outdoor. 14 Apr 2019: The owner applied one tube of FRONTLINE PLUS CATS (lot unknown, package unavailable) topically between the shoulders to each cat. No fleas were seen at the time. 12 May 2019: The owner applied one tube topically between the shoulders to each cat. No fleas were seen at the time. 01 Jun 2019: The owner saw 5-6 fleas on the cats. 06 Jun 2019: The owner applied one tube topically between the shoulders to each cat. 13 Jun 2019: The owner saw 1-2 fleas on the cats. There are no other pets in home. No further medical information expected.
13-Jun-2019	UAE; 19US033981; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Month(s) **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?:** Unknown to Company	13-May-2019*	13-Jun-2019*	31 Day(s)	D-D	Suspected Adverse Event: 13 Jun 2019: An owner reported the following event in an unknown dog; 10 months old, male, unknown repro status, breed, and weight. 13 May 2019*: The dog was scratching. The owner applied one vial FRONTLINE PLUS DOGS *product unsubstantiated (lot unknown, package unavailable) between the shoulder blades topically. 13 Jun 2019*: The dog is still scratching. The owner believes the dog has allergies. The owner was calling to confirm online retailer, not to report event. No further medical information available.

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13-Jun-2019	UAE; 19US034018; MA; U.S.A	**Species:** Canine **Breed:** Pekingese **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 17.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Malaseb; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Mar-2019	09-Jun-2019*	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 13 Jun 2019, the animal owner reported the following event for Harley, a 11 year old*, 17.0 pound, neutered male Pekingnese Shih Tzu Mix. 01 Mar 2019 through 01 Jun 2019: He received FRONTLINE PLUS 5-22 LBS (lot and expiration unknown) one dose applied topically monthly, seasonally between the shoulders. 09 Jun 2019*: The owner noticed a large amount of fleas on the dog and off of the dog inside the household. The dog does get bathed one to two times a month with Malaseb. The owner did treat the dog on an unknown date with an unknown flea shampoo. He has not presented to the veterinary clinic. His current condition is ongoing. There are no other pets in the household. He has a pertinent medical history of atopic dermatitis and undefined cardiac murmur. No further medical information expected.
13-Jun-2019	UAE; 19US034024; CA; U.S.A	**Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** X **Sex qualifier:** Neutered **Age:** 19.00 Year(s) **Weight:** 10 - 10 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Prednisone; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Mar-2019*	13-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 13 Jun 2019, the pet owner reported the following event for 2 cats, females spayed, 10 pounds, 19 years old, Feline mixed/ various breeds. Unknown dates: Both cats have taken prednisone steroid. 13 Mar 2019*: The pet owner first noticed 1-5 fleas on the cats. 12 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S40603AW) topically to hair between the shoulder blades of the cats on monthly basis with fleas present. 13 Jun 2019: The pet owner saw increase in fleas with 15+ fleas. The cats were in good health at time of application. The cats were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen fleas in the home jumping and biting. The cats have no history of skin problems or any other issues with topical treatments. The cats have not had flea problem before in the past. The cats have not received any other topical treatments. The cats have not been bathed. The cats are indoors. The current status of the cats are unknown. No further medical information.
13-Jun-2019	UAE; 19US034026; SC; U.S.A	**Species:** Canine **Breed:** Beagle **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?:** Yes	09-Jun-2019	13-Jun-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Jun 2019, the pet owner reported the following event for Bloom, a 5 year old 25 pound female spayed Beagle mix. 8 May 2019 and 9 Jun 2019: The dog was given a dose of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) for its first 2 doses. There were several days after each dose where the pet owner saw fleas on the dog and then treated with Capstar. There were no fleas on the dog prior to application. There is another dog and cat in the home, all of which are inside/outside pets. The other pets are on Sentry but they have not seen any fleas on these pets and have not seen fleas in the home. The pet owner saw fleas on the dog again in the last few days. No further medical information expected.
13-Jun-2019	UAE; 19US034036; HI; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.50 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 /	15-Jan-2019*	31-May-2019*	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 13 Jun 2019, the pet owner reported the following event for Winnie, a 1.5 year old, 45 pound*, spayed female, Dachshund/Terrier mix. Jan 2019 (unknown dates): The canine was adopted from a shelter by the reporter. An unknown date following adoption, the reporter purchased 6 doses of FRONTLINE PLUS DOG 45-88 LBS (X60719AX) from Costco. 15 Jan 2019*: She began receiving one vial of FRONTLINE PLUS DOG 45-88 LBS (X60719AX), applied topically between the

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						Cutaneous **Was the product used ok?:** Yes					shoulder blades. One vial has since been applied monthly around the fifteenth. 15 May 2019*: The most recent application of the product was administered. 31 May 2019*: The began finding fleas on Winnie. It couldn't be confirmed how many fleas she was finding on the canine. Unknown dates: Winnie was bathed with a multitude of unknown products and has also received unknown applications of Apple Cider Vinegar, unknown essential oils, other unknown vinegar, and Diatomaceous Earth. She was not bathed within 24 hours following FRONTLINE PLUS application though the frequency of bathing couldn't be confirmed. Although the reporter never found any fleas in the home or getting onto her, she has vacuumed and shampooed her carpets and furniture at least three times as well as washed various linens in the home. She's also treated the house with various products including but not limited to boric acid, and baking soda. On additional unknown dates, her parent's 60 pound dog briefly visited the home to play with Winnie, but was primarily kept outside in the yard. Said canine also receives FRONTLINE PLUS DOG 45-88 LBS applied monthly year round as previously described. 11 Jun 2019: Winnie was bathed again with an unknown product. 13 Jun 2019: While on the phone with the reporter, at quick glance (no more than 15 seconds), she estimates seeing approximately 8 live fleas on Winnie. There are no other dogs in the home. Winnie is primarily kept in the home but is able to go in their yard
13-Jun-2019	UAE; 19US034051; TX; U.S.A	**Species:** Canine **Breed:** Dalmatian **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 50 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN CHEWABLE 68 MCG; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-May-2019	19-May-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 31 May 2019, the pet owner reported the following event for Lexus a female spayed, 50 pound, 1 year old, Dalmatian. Unknown dates: The pet owner administers unknown amount of HEARTGARD CHEWABLE (lot number unknown, expiration unknown) (product unsubstantiated) PO to Lexus. 18 May 2019: The pet owner noticed 5-15* fleas on the body of Lexus. The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (S62202AX) topically to skin between the shoulder blades of Lexus monthly on year round basis. 19 May 2019: The pet owner continued to see 15+ fleas on the body of Lexus. Lexus was in good health at time of application. Lexus was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen any fleas in the home. Lexus has no history of skin problems or any other issues with topical treatments. Lexus has not had flea problem before in the past. Lexus has not received any other topical treatments. Lexus has not been bathed. Lexus is indoors and outside in fenced yard. The current status of Lexus is unknown. Lexus shares home with one other dog in the home treated with FRONTLINE PLUS DOG 5-22 LBS (S61718AL) with case number 19US030617. No further medical information.
13-Jun-2019	UAE; 19US034062; MO; U.S.A	**Species:** Canine **Breed:** Setter (Irish) **Sex:** F **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	01-Jun-2019	06-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 13 June 2019, the owner reported the following event for a canine (all other signalments unknown). 2016*: The dog started on FRONTLINE PLUS on a monthly basis year round. 13 June 2019: The most recent vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades,

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		Age: 3.00 Year(s) **Weight:** 50 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					by the pet owner. 14 June 2019*: The dog had a small amount of fleas. The dog does not get bathed. The owner is not seeing flea activity in the home. The dog goes outside for bathroom breaks. No further medical information is expected. UPDATE": 24 JUN 2019: The pet owner reported the following event for Katty a 3 year old, 50 pound female spayed Setter (Irish). *2016: The owner started applying FRONTLINE PLUS DOG 45-88 LBS (S62408AX) for the first time and repeated on a monthly and year round basis. 1 Jun 2019: The owner applied a dose. *6 Jun 2019: The owner noticed fleas for the first time. 8 Jun 2019: The owner applied another dose. 9 Jun 2019: The owner continued seeing fleas. *17 Jun 2019: The dog presented to the vet clinic and was started in Bravecto. 12 hours later the owner no longer saw fleas. There are no other pets in the home. No further medical information expected.
12-Jun-2019	UAE; 19US034101; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 22.00 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-Apr-2019	01-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 Jun 2019, Animal owner reported an event in her 22 year old cat. 01 Apr 2019: The pet owner noticed live fleas on the cat and applied the full contents of 1 vial of FRONTLINE PLUS CATS (Lot unknown) topically in an unknown location for the first time. 01 Jun 2019: The pet owner is still noticing live fleas and flea dirt on the cat and applied the full contents of 1 vial of FRONTLINE PLUS CATS (Lot unknown) topically in an unknown location. There is one other cat in the home (reported in case 19US033764). The pet owner has not seen fleas in the home but had the environment treated. No further information expected.
13-Jun-2019	UAE; 19US034107; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Prednisone; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	08-Jun-2019	12-Jun-2019	4 Day(s)	D-D	Suspected Adverse Event Claim: On 13 Jun 2019, animal owner reported the following event for Romeo, a 5 year old, 10 pound, neutered male, domestic shorthair cat. 08 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (Lot unknown) topically between the shoulder blades for the first time. 12 Jun 2019: The pet owner noticed flaky skin and alopecia at the application site. A sebacious cyct was noted near the application site. The attending veterinarian advised to apply neosporin to the application site. The patient has a history of skin issues and currently takes prednisone 1.5ml SID. The patient has issues with hair growning in very slow from a previous ultrasound. No further information expected.
13-Jun-2019	UAE; 19US034120; TN; U.S.A	**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:** FIPRONIL 9.8% / S-METHOPRENE 11.8% /	30-May-2019	30-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 13 June 2019 , the owner reported the following event for 11 indoor cats (signalment unknown). 30 May 2019: The cat had fleas and one vial of FRONTLINE PLUS CATS (S41307AW) was applied topically to the skin between the shoulder blades for the first time (the owner was not able to apply all the product to the skin on all the cats). *Unknown date: The cats started to pick up a medium quantity of fleas and started to itch and scratch. The cats are usually treated with FRONTLINE GOLD FOR CATS (lot unknown) monthly year round and never had an issues with

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						PYRIPROXYFEN 0.25% TOPICAL SOLUTION; Oatmeal shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					fleas while on that medication. All the cat have a medium quantity of fleas and there have been fleas in the home for the past month. There are 8 cats with skin issues who are bathed with oatmeal shampoo. The owner mentioned they are having an issue with raccoons hanging out on the porch, there also may have been a lapse in treatment. No further information available.
13-Jun-2019	UAE; 19US034130; NY; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 72 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 272MCG/652MG ; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	13-Apr-2019	20-May-2019	5 Week(s) 2 Day(s)	D-C	Suspected Adverse Event: On 13 June 2019 the owner reported the following event for Larkin, a 10 year old, 72 pound, spayed female Retriever (Golden). 13 April 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S62202AX) was applied to the skin between the shoulder blades. 20 May 2019: The dog's entire underside and inside of her legs became bright pink and red. Her skin was dry and crusty and her nipples were enlarged. 28 May 2019: The dog was taken to the vet and received an unknown injection. Larkin symptoms are still better but still ongoing. She had the same reaction in Jan, she used Virbac Ketochlor shampoo and given antibiotic and the symptoms cleared in a week. Larkin has been on FRONTLINE PLUS all her life and never had an issue prior to Jan 2019. The dog also takes HEARTGARD PLUS (272 MCG/227 MG) (lot and expiration unknown) and has been on this medication all her life with no issues. No further information available.
13-Jun-2019	UAE; 19US034131; TN; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 6.1 lbs	3	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?:** No (Indication not indicated / recommended)	05-Jun-2019	05-Jun-2019	0 Day(s)	D-A	Suspected Adverse Event/Lack of efficacy: On 13 Jun 2019, the owner reported the following event for Beth, 1 year old, 6.1 pound, female neutered, Domestic Shorthair. 5 June 2019: One vial FRONTLINE PLUS CATS (S40603AW) was applied topically in between the shoulder blades in one location. Within 24 hours the cat became extremely lethargic and in extreme pain when touched or palpated. The pet was presented to the emergency clinic. A CBC/CHEM was performed and the cat was diagnosed with Bobcat Fever from a tick bite. It is unknown what treatment the cat was given. 9 Jun 2019: The cat was euthanized. This cat has been on FRONTLINE PLUS CATS off and on since 2018.There are 2 other cats within the home using the product and did not experience any adverse events. No further medical information expected at this time. UPDATE 2 Jul 2019 per medical records received on 18 Jun 2019: 5 June 2019: The pet presented to the clinic for having a tick on the medial canthus of her right eye, weight loss, not eating or drinking, fever that began on 4 Jun 2019, laying around, and limping on her left rear leg. The pet's temperature was 104.7 F. Blood work revealed the following abnormalities: HCT decreased 27.8%, Hb decreased 93, decreased reticulocytes/Hb 12.5,

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											decreased WBC 2.34, decreased neutrophils 1.63, bands suspected, decreased lymphocytes 0.48, decreased eosinophils 0.03, decreased platelets 17; increased glucose 221, increased total bilirubin 4.3, and decreased alkaline phosphatase less than 10. No platelets were noted on a blood smear; ghost red blood cells were noted, as well as significantly decreased WBC. The veterinarian suspected cytauxzoon felis. The pet was treated with dexamethasone, Convenia, and SC fluids. 6 Jun 2019: Piroplasms were observed on a new blood smear confirming the diagnosis of cytauxzoon felis. No further medical information expected.
14-Jun-2019	UAE; 19US034140; IN; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** - **Age:** 6.00 Month(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	11-Jun-2019	12-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 14 Jun 2019, the pet owner reported the following event for Casey, a 6 month old, 54 pound, intact male Golden Retriever. 11 Jun 2019: The owner applied 1 dose of FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown) topically between the shoulder blades. 12 Jun 2019: The dog began experiencing inappetance, vomiting, diarrhea along with ocular discharge. No treatment has been performed at this time and the dog's symptoms are persistent. No further medical information expected.
14-Jun-2019	UAE; 19US034141; NY; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 12 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** PO-Oral **Was the product used ok?:** Yes	11-Jun-2019	11-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 14 Jun 2019, the pet owner reported the following event for Sophie, a 12 pound, 10 to 12 year old*, male neutered, Domestic Short hair (Crossbreed). 20 Apr 2019: The cat was having an issue with fleas. The owner took the cat to the veterinarian where he was given an unknown dose of capstar and 1 vial of Revolution was applied. 21 Apr 2019*: The cat had a skin reaction at the application site, his hair fell out and the application site was red and irritated. 1 May 2019*: The cat recovered. 11 Jun 2019: The flea issue was ongoing. The owner purchased FRONTLINE PLUS CATS (S41003AW) from Pet Smart .1 vial was applied to the cat in area between the shoulder blades horizontally. The application site became red and irritated 1 hour after the application. The cat loss more area and is almost bald. The application site has scabs and is red. The owner applied neosporin. The cat was not seen by the veterinarian. No further medical information is expected.
14-Jun-2019	UAE; 19US034149; NC; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** - **Age:** 3.00 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	01-Jan-2019*	02-Jan-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, the owner reported the following event for Tino, 3 year old, 11 pound, intact male, Chihuahua mix canine. 1 Jan 2019: The dog began receiving monthly doses of FRONTLINE PLUS DOG 5-22 LBS (lot unknown). One vial was applied between the shoulder blades. 2 Jan 2019*: The owner noticed a small number of fleas and the dog itching. 1 May 2019: The most recent vial was applied. 2 May 2019*: The owner found 1 flea on the pet. The flea was removed. 14 Jun 2019: No fleas were noted at the time of the report but the itching was still ongoing. The dog has received the product in on prior unknown dates with

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											no issue. There are no other pets in the household. No further medical information is expected.
14-Jun-2019	UAE; 19US034233; NJ; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 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 ok?:** Yes	01-Jun-2019	14-Jun-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, the pet owner reported the following event for Bella, a 5 pound, 1 year old, female spayed, Domestic Shorthair. 1 Jun 2019: 1 vial of FRONTLINE PLUS CATS (S40502AX) was applied to the cat in one area between the shoulder blades. 14 Jun 2019: The owner found 2 ticks on the cat, and removed them. The cat is indoor/outdoor. The owner treats seasonally, 1 Apr 2019 first application of the season. The cat has not history of skin isses and has not had a bath. No further medical information is expected.
14-Jun-2019	UAE; 19US034251; CA; U.S.A	**Species:** Canine **Breed:** Poodle (Standard) **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	10-Jun-2018*	12-Jun-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, the pet owner reported the following event for Olive Brown, a 3 year old, 70 pound, spayed female Poodle mix. Jun 2018*: The dog began receiving year-round, monthly doses of FRONTLINE PLUS DOG 45-88 LBS (R62301AR) with the most recent dose purchased from Amazon.com and applied on 10 Jun 2019. 12 Jun 2019*: The owner noticed less than 10 live fleas on the dog. She bathed the dog and found approximately 5 more fleas and found an additional flea in the home in an area where the dog sleeps. Per the owner, the dog has never had an issue with fleas on the product before. There are no other animals in the home and the dog was not bathed after FRONTLINE PLUS application. The dog goes outside in the yard occasionally and occasionally goes to the groomer although she dog was not bathed within 24 hours of application. No further medical information expected.
14-Jun-2019	UAE; 19US034256; OH; U.S.A	**Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 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-May-2019	02-Jun-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, the pet owner reported the following event for Gipsy a female intact, 10 pound, 4 year old, Poodle/Schnauzer crossbreed. 2 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S61721AL) topically to skin between the shoulder blades of Gipsy monthly on year round basis. 2 Jun 2019: The pet owner noticed 6 attached alive ticks on the body of Gipsy. Gipsy was in good health at time of application. Gipsy was not presented to veterinarian. Gipsy has no history of skin problems or any other issues with topical treatments.Gipsy has not had problem in the past. Gipsy has not received any other medications or topical treatments. Gipsy has not been bathed. Gipsy is indoors and outside. The current status of Gipsy is unknown. No further medical information.
14-Jun-2019	UAE; 19US034258; CA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products	10-Dec-2018*	17-Dec-2018*	N/A	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, a pet owner reported the following event for Reina, a 5 year old, 11 pound, spayed female Domestic Shorthair. 10 Dec 2018*: The cat began receiving monthly FRONTLINE PLUS CATS (S41003AW) topically between the shoulder blades because the pet owner was seeing fleas on the cat. 17 Dec 2018*: The pet owner noticed a couple of live fleas on the cat.

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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: 11 lbs				**Route:** Topical / Cutaneous **Was the product used ok?:** Yes					27 May 2019: The most recent dose of FRONTLINE was applied. The pet owner stated that she has continued to see 1-2 live fleas after each application since Dec 2018 and over the past few weeks has seen 10 live fleas on the cat. She is concerned that this is a bad batch of FRONTLINE that she purchased from Chewy. There is 1 other cat in the home that also has fleas and is on FRONTLINE, see case 19US035257. There are 2 dogs in the home, 1 is on FRONTLINE and 1 is on Bravecto. The pet owner is not noticing fleas on the dogs. No further information expected.
14-Jun-2019	UAE; 19US034271; -; 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	01-Mar-2019*	14-Jun-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, Owner reported the following event for 2 dogs. *01 Mar 2019 - 01 May 2019: The pet owner applied FRONTLINE PLUS DOG 0-22 LBS (Lot unknown) in an unknown location along with Comfortis for a recurring flea issue. 14 Jun 2019: The pet owner reported still seeing live fleas. The owner declined providing case details. All information is approximated for reporting purposes. No further information expected.
26-Jun-2019	UAE; 19US034282; CO; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 15 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	12-Jun-2019	13-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On14 Jun 2019, the pet owner reported the following event for Toby a male neutered , 15 pound, 8 year old, Small crossbred. 12 Jun 2019: The pet owner bathed dog with unknown shampoo. The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S61212AL) topically to skin between the shoulder blades of Toby for the first time. 13 Jun 2019: The pet owner noticed 15+ fleas on the body of Toby. 14 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS opically to skin between the shoulder blades of Toby for second time. Toby was in good health at time of application. Toby was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. Toby has no history of skin problems or any other issues with topical treatments. Toby has not had flea problem before in the past. Toby has not received any other medications or topical treatments. Toby is indoors and outside. Toby shares home with one other dog that is treated with unknown amount of FRONTLINE PLUS that has no flea issues. The current status of Toby is unknown. No further medical information. UPDATE 26 Jun 2019: Case changed to an inquiry due to preexisting fleas and product only administered one month.
14-Jun-2019	UAE; 19US034299; -; 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**	12-Jun-2019	13-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 14 Jun 2019, the pet owner reported the following event for a canine of unknown signalment. 12 Jun 2019: The dog received 1 dose of FRONTLINE PLUS DOG (product unsubstantiated) (lot and expiration unknown) applied topically between the shoulder blades by the owner. 13 Jun 2019: The dog began experiencing diarrhea. The current status of the dog is unknown. Per the owner, the dog has received FRONTLINE in the past without issue and other dogs in the home who do not receive FRONTLINE are currently experiencing similar symptoms. No further medical information expected.

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						product used ok?: Unknown to Company					
14-Jun-2019	UAE; 19US034301; CA; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 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	04-Jun-2019	06-Jun-2019*	2 Day(s)	D-D	Suspected Adverse Event: On 14 Jun 2019, a pet owner reported the following event for Chula, a 12 year old 5 pound spayed female Chihuahua. 7 Mar 2019: The owner applied FRONTLINE PLUS DOG 5-22 (lot unknown) topically unknown where it was applied on the dog. 9 Mar 2019*: The dog has a seizure like episode, and was flopping around on the ground uncontrollable. The owner is not sure of the date, she said she could not remember. 4 Jun 2019: The owner applied FRONTLINE PLUS DOG 5-22 (lot unknown) topically unknown where it was applied on the dog. 6 Jun 2019*: The dog has a seizure like episode, and was flopping around on the ground uncontrollable. The owner is not sure of the date, she said she could not remember. The dog was never taken to a veterinarian for evaluation or treatment. There is another dog in the house that had a similar issue, see case 19US034306. No further medical information expected.
14-Jun-2019	UAE; 19US034306; CA; U.S.A	**Species:** Canine **Breed:** Terrier Breeds (500 Series) **Sex:** U **Sex qualifier:** Unknown **Age:** - **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	04-Jun-2019	06-Jun-2019*	2 Day(s)	D-C	Suspected Adverse Event: On 14 Jun 2019, a pet owner reported the following event for Kira, a 13 pound Terrier of further unknown signalment. Unknown Date: The dog was scratching prior to having any products applied. 4 Jun 2019: The owner applied FRONTLINE PLUS DOG 5-22 (lot unknown) topically unknown where it was applied on the dog. 6 Jun 2019*: The dog has a seizure like episode. The dog had bloody stools and had a hard time standing up, her front legs did not want to hold her up. The owner is not sure of the date, she said she could not remember. The dog was never taken to a veterinarian for evaluation or treatment. There is another dog in the house that had a similar issue, see case 19US034301. No further medical information expected.
14-Jun-2019	UAE; 19US034347; CA; U.S.A	**Species:** Canine **Breed:** Collie **Sex:** F **Sex qualifier:** - **Age:** - **Weight:** 65.000 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	12-Jun-2019*	14-Jun-2019	2 Day(s)	D-D	Suspected Adverse Event:On 14 June 2019, the owner reported the following event for a 60 pounds, Collie (all other signalments unknown). Unknown date: The pet owner stated that the dog has been on FRONTLINE PLUS before but not sure of the date. 12 June 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S62401RX) was applied between the shoulder blades, by the pet owner. 14 June 2019: The dog had discoloration of the fur at the area of application, it was white and turned yellow. No further medical information is expected. UPDATE 20 JUN 2019: Per the owner: Niska is a 60 pound, intact female Rough Collie. No further medical information expected.
14-Jun-2019	UAE; 19US034368; CA; U.S.A	**Species:** Canine **Breed:** Cavalier King Charles **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 22 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** AFOXOLANER 28.3 MG	12-Jun-2019	13-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event and Suspected Lack of Efficacy Claim : On 14 Jun 2019, the pet owner reported the following event for Rhianon, an 8 month old 22 pound intact female Cavalier King Charles. 12 Jun 2019: The dog was given a chew of NEXGARD (28.3 mg) (AA203717A, Oct 2019) for the first time for fleas. She was also given a dose of FRONTLINE PLUS DOG 23-44 LBS (lot unknown). 13 Jun 2019: The dog presented to a clinic for scabs from the fleas

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						CHEWABLE TABLETS; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					and started vomiting on the drive there. The clinic treated with Cerenia. 14 Jun 2019: The dog has continued to vomit. There are 3 other dogs in the home who are also on FRONTLINE and have fleas see case 19US034373. The pet owner lives out in the country but there are no fleas in the home. The dog has been receiving FRONTLINE since Feb 2019*. No further medical information expected.
14-Jun-2019	UAE; 19US034398; ND; 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	03-Jun-2019	14-Jun-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 June 2019, the owner reported the following event for a canine (all other signalments unknown). 3 June 2019: One vial of FRONTLINE PLUS DOG 5-22 (lot unknown) was applied between the shoulder blades, by the pet owner. 14 June 2019: The dog had 20 ticks. The pet owner removed all the ticks. It is unknown if the dog gets bathed or has any skin issues. The owner is not seeing any tick activity in the home. No further medical information is expected.
14-Jun-2019	UAE; 19US034430; AL; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Neutered **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	11-Jun-2019*	14-Jun-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019 the pet owner reported the following event for an Sophie a 4 year old 8 pound female spayed small crossbred (<10 kg). *7 Jun 2019: The owner adopted the dog and did not notice any fleas. *11 Jun 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 5-22 LBS (UNKNOWN) to the skin between the shoulder blades for the first time. 14 Jun 2019: The owner noticed 1 flea. There are no other pets in the home. The owner is not noticing any indoor flea activity. The dog is mainly indoors but goes outside into an unfenced yard. The dog does not get baths and unknown about the skin condition of the dog. No further medical information expected.
14-Jun-2019	UAE; 19US034458; CA; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various **Sex:** X **Sex qualifier:** Mixed **Age:** 2.00 Year(s) **Weight:** 10 - 16 lbs	8	8	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Crystal whitening shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Apr-2019	12-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 5 Jun 2019, the pet owner reported the following event for 8 dogs, mixed sexes, mixed reproduction statuses, 10-16 pounds, 2-15 years old, Mixed breeds/ various breeds. 11 Apr 2019: The pet owner first noticed 1-5 fleas on the dogs. The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S60401AX) topically to skin between the shoulder blades of the dogs on monthly basis for the first time. 11 May 2019: The pet owner bathed the dogs with Crystal whitening shampoo. The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS topically to skin between the shoulder blades of the dogs on monthly basis. 11 Jun 2019: The pet owner bathed the dogs with The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS topically to skin between the shoulder blades of the dogs on monthly basis. 12 Jun 2019: The pet owner continued to see 1-5 fleas on the dogs. The dogs were in good health at time of application. The dogs were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has seen fleas in the

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											home jumping and biting. The dogs have no other issues with topical treatments but one dog has hotspot on the back of her neck. The dogs have not had flea problem before in the past. The dogs have not received any other medications or topical treatments. The dogs are indoors and outside in fenced yard. The current status of the dogs are unknown. No further medical information.
15-Jun-2019	UAE; 19US034462; FL; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 18 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown flea medication; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	24-May-2019*	24-May-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 June 2019,the owner reported the following event for an 18 pound dog (signalment unknown). *24 May 2019: The dog may have had fleas (owner is not sure) before the application and one vial of FRONTLINE PLUS DOG 5-22 LBS (FL) (L63507AL) was applied to the skin between the shoulder blades for the first time. *Unknown date: Owner found 100 plus fleas on the dog. 14 June 2019: Another application of FL was applied. The dog is exposed to the outdoor environment and that is when the owner is finding fleas after he walks his dog. The dog was on a different flea medication prior to FL. There are no fleas in the home and the yard is treated. There are no other dogs in the home. No further information available.
14-Jun-2019	UAE; 19US034463; TN; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 25 - 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?:** No (Treatment / vaccination program not respected)	14-May-2018*	13-May-2019	29 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, the pet owner reported the following event for 3 dogs, Spencer,a male neutered, 30 pounds, 13 years old, Mixed breeds/ various breeds, Snickers, a male neutered, 7 year old, 25 pound, Dachshund, and Hershey, a male neutered, 25 pound, other signalment unknown. 13 May 2019: The pet owner first noticed 1-5 fleas on the dogs. 14 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 23-44 LBS (S60713AX) topically to skin between the shoulder blades of the dogs on monthly basis. 15 May 2019: The pet owner continued to see 1-5 fleas on the dogs. 9 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 23-44 LBS topically to skin between the shoulder blades of the dogs on monthly basis. The dogs were in good health at time of application. The dogs were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has seen fleas in the home jumping and biting her. The dogs have no history of skin problems or any other issues with topical treatments. The dogs have not had flea problem before in the past. The dogs have not received any other medications or topical treatments. The dogs are indoors and outside in fenced yard. The current status of the dogs are unknown. The dogs share home with one other dog that is treated with FRONTLINE PLUS DOG 45-88 LBS (S61603AX) with case number 19US034465. No further medical information.
14-Jun-2019	UAE; 19US034465; TN; U.S.A	**Species:** Canine **Breed:** Collie **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 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 /	14-May-2018*	13-May-2019	29 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, the pet owner reported the following event for Hunter, a male neutered, 12 year old, 75 pound, Collie. 13 May 2019: The pet owner first noticed 1-5 fleas on the dog. 14 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (S61603AX) topically to skin between the shoulder blades of the dog on monthly basis. 15 May 2019: The pet owner continued to see 1-5 fleas on the dog. 9 Jun 2019: The pet owner applied one dose of FRONTLINE

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						Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					PLUS DOG 45-88 LBS topically to skin between the shoulder blades of the dog on monthly basis. The dog was in good health at time of application. The dog was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has seen fleas in the home jumping and biting her. The dog has no history of skin problems or any other issues with topical treatments. The dog has not had flea problem before in the past. The dog has not received any other medications or topical treatments. The dog is indoors and outside in fenced yard. The current status of the dog is unknown. The dog share home with one other dog that is treated with FRONTLINE PLUS DOG 23-44 LBS (S60713AX) with case number 19US034463. No further medical information.
17-Jun-2019	UAE; 19US034510; AR; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** Neutered **Age:** 2.50 Year(s) **Weight:** 8 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 ok?:** Yes	01-Jun-2019	10-Jun-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the pet owner reported the following event for Jet, a 2.5 year old, 8 pound, neutered male, Chihuahua Dachshund Mix. 15 May 2019: The owner gave a dose of HEARTGARD PLUS(68 MCG/57 MG)(lot and expiration unknown). Owner tried to find lot number but states it appears she ripped it off by accident when splitting the chews. 1 Jun 2019: He received his monthly dose of FRONTLINE PLUS DOG 5-22 LBS (S62502AW). He has been on FRONTLINE monthly since 2017*. 10 Jun 2019: The owner noticed fleas on Jet. The dog is dosed correctly with the proper usage. The dog does frequent outside for walks and potty breaks. The owner's yard is fenced in and she states there are other animals in the neighborhood. The owner stated she treats her yard with a insecticide granule. The owner is seeing around 10 fleas daily in the household, and on has seen one on her own person. Though she has not yet been bitten. He began experiencing itching when the fleas became present on the animal. The owner stated she had seen fleas before in the summer or spring of 2018, but the exact dates are unknown. His current condition is ongoing. No further medical information expected.
17-Jun-2019	UAE; 19US034538; -; 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?:** No (Treatment / vaccination program not respected)	18-Apr-2019	17-Jun-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the owner reported the following event for a 80 pound canine of unknown signalment. 2018*: Dog started monthly on FRONTLINE PLUS DOG 45-88 LBS (Lot and Expiration Unknown) topically in between the shoulder blades. Apr 2019*: An unknown amount of fleas were seen on the dog. One dose of FRONTLINE was applied topically in between the shoulder blades on 18 Apr 2019, 4 May 2019, and 30 May 2019. 17 Jun 2019: The owner reports to have seen increased itching and scratching. There is 1 other dog in the home that is also on FRONTLINE (Please see case 19US034529). The dog is primarily indoors other than walks outside. No further information at this time.
17-Jun-2019	UAE; 19US034540; OK; U.S.A	**Species:** Canine **Breed:** Retriever (Golden)	1	1	0	**Product used:** FIPRONIL 10%/S	02-Jun-2019	03-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the owner reported the following event for Volero, 10 year old, 85 pound, neutered male, Golden Retriever canine.

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		Sex: M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 85 lbs				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)					2 Jun 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (S62311RX) was applied between the shoulder blades for the first time this year. 3 Jun 2019: The owner continued to find fleas on the dog. 17 Jun 2019: The owner has continued to find fleas on the pet. The dog has received the product on prior unknown dates with no issue. There is 1 outdoor cat that is not being treated, it is unknown if the cat has fleas. No further medical information is expected.
17-Jun-2019	UAE; 19US034552; NJ; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** - **Age:** 5.00 Month(s) **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	16-Jun-2019	16-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 17 Jun 2019, the pet owner reported the following event for Chip, a 5 month old 48 pound intact male German Shepherd. 16 Jun 2019: The pet owner applied a dose of FRONTLINE PLUS DOG 45-88 LBS (S62408AX) between the shoulder blades down to the skin. That night, the dog started scratching at the application sight and under his abdomen. The dog's status was the same at the time of the phone call. The dog had the same reaction after the 14 May dose. No further medical information expected.
12-Jun-2019	UAE; 19US034564; VA; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** - **Age:** 1.50 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?:** Unknown to Company	15-May-2019	27-May-2019*	12 Day(s)	D-D	Suspected Lack of Efficacy: On 12 Jun 2019 the owner reported the following event for Lela, a 1 year old, 12 pound, intact female, Chihuahua. 15 May 2019: The owner applied first dose of FRONTLINE PLUS to Lela as directed by the box. 22 May 2019*: The owner was seeing fleas on the dog. The dog does go out in the yard to play and potty from time to time. While she gets bathed it is only when needed, and the owner waits 24 hours after use of FRONTLINE. The owner uses a scented shampoo for bathing, and flea combs the animal daily. The owner also treats the inside of the house with baking soda followed by vacuuming. The animal is itching, but the owner stated that started with the fleas. She is seeing about 3 to 10 plus fleas on the animal daily. She has had a reaction to Zodiac that caused severe itching, but this reaction stopped after switching off that product . The other Chihuahuas in the house also had a similar event and had a case reported at this time, see 19US030873. No further information is expected.
17-Jun-2019	UAE; 19US034570; MN; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 24.00 Month(s) **Weight:** 14.1 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	13-Aug-2018	13-Aug-2018	0 Day(s)	D-D	Suspected Adverse Event: On 17 Jun 2019 the clinic staff reported the following event for Remy, a 24 month old (born 13 Aug 2016), *14.1 pound, neutered male Yorkshire Terrier. 13 Aug 2018: The canine received FRONTLINE PLUS DOG 5-22 LBS (lot unknown), unknown, volume, route, or application site. At an unknown time following application on the same date, the canine began experiencing generalized pruritus. The patient presented to the clinic and was treated with Amoxicillin and Cytopoint. The pet owner discontinued use of FRONTLINE PLUS. 15 Aug 2018*: The canine recovered. Remy experienced a reaction after receiving NEXGARD on 13 Jun 2019 (see case number 19US034569). No further medical information 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
17-Jun-2019	UAE; 19US034604; IN; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 62.00 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Episoothe Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	02-May-2019	09-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the pet owner reported the following event for a 62 pound, male, Large crossbred (>20 KG). All other signalments unknown. 2 May 2019: 1 vial of FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown) was applied to the dog in one area between the shoulder blades for the very first time of the season. The dog was not having an issue with fleas prior to this application. 1 Jun 2019*: The dog was bathed in episoothe shampoo. 9 Jun 2019: 1 vial of FRONTLINE was applied to the dog. The owner has seen 2 fleas on the dog since this application. The owner treats seasonally, the last application was summer 2018. The dog goes out for potty breaks and recreation in the yard where there are urban wildlife present. There are no fleas in the home. The dog does not have a history of skin issues. There are no other pets in the home. No further medical information is expected.
17-Jun-2019	UAE; 19US034658; VA; U.S.A	**Species:** Canine **Breed:** Australian Sheep Dog **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 20 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	01-Jan-2019	04-Jun-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the pet owner reported the following event for a 20 pound*, Australian Sheep Dog. All other signalments unknown. 4 Jun 2019: 1 vial of FRONTLINE PLUS DOG 5-22 LBS(lot and expiration unknown) was applied to the dog in one area between the shoulder blades. The owner has been seeing a small amount of fleas on the dog everyday since the appliecation. The owner bathed the dog in an unknown shampoo to remove the fleas. The owner has been seeing fleas on the dog daily since the bath. The owner has been treating with FRONTLINE monthly since Jan. 2019. There is one other dog in the home who was treated with FRONTLINE, see case 19US36381. There are no fleas in the home. The dog has no history of skin issues. The dogs go out for potty breaks and recreation in a yard where fleas are present. The owner has treated the yard. No further medical information is expected.
17-Jun-2019	UAE; 19US034662; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **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	15-May-2019	16-May-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the owner reported the following event for a 13 pound feline (all other signalments unknown). 30 Apr 2019: The cat started scratching. 15 May 2019: The owner took the cat to the veterinarian who applied 1 dose of FRONTLINE PLUS CATS (R41118AW) topically between the shoulder blades. The veterinarian did not confirm that the cat had fleas. 16 May 2019*: The owner started seeing a small amount of fleas on the cat. The owner is not seeing fleas in the home but does have a few flea bites on her. The cat is indoor/outdoor and is able to roam outside in a wooded area. No further medical information expected.
17-Jun-2019	UAE; 19US034665; CA; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 25 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	08-Jun-2019	10-Jun-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 June 2019, the owner reported the following event for Can can, 6 years old, 25 pounds, neutered male, Chihuahua. 8 June 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (R62420BL) was applied between the shoulder blades, by the pet owner. 10 June 2019: The dog had a small amount of fleas. The dog has been bathed or gone swimming. The dog does not have any skin issues. The owner has fleas in the home biting her

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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
						Route: Topical / Cutaneous **Was the product used ok?:** Yes					and her husband. The dog goes out into a back yard with dirt and cement. There is 1 other dog and 3 cats in the home that have not been treated with any flea preventative. No further medical information is expected.
17-Jun-2019	UAE; 19US034673; TX; U.S.A	**Species:** Canine **Breed:** Pomeranian **Sex:** M **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 21 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 ok?:** Yes	29-May-2019	15-Jun-2019*	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jun 2019, the pet owner reported the following event for Oreo a male neutered, 21 pound, 13 year old, Pomeranian/ samll crossbreed. 29 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (P62719AL) topically to skin between the shoulder blades of Oreo and uses on a year round basis monthly. The pet owner administered an unknown HEARTGARD (lot number unknown, expiration unknown) (product unsubstantiated) 1 chew, PO. 15 Jun 2019*: The pet owner first noticed 1-2 fleas on the body Oreo. 17 Jun 2019: The pet owner bathed the dog with Biochem shampoo. Oreo was in good health at time of application. Oreo was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. Oreo has no history of skin problems or any other issues with topical treatments. Oreo has not had flea problem before in the past. Oreo has not received any other topical treatments. Oreo is indoors and outside in fenced yard. The current status of Oreo is unknown. No further medical information.
17-Jun-2019	UAE; 19US034674; PA; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 1.50 Year(s) **Weight:** 9.0 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	21-May-2019	10-Jun-2019	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the animal owner reported the following event for Coco, a 1.5 year old*, 9.0 pound, spayed female Yorkshire Terrier Chihuahua Mix. Jan 2018* through 21 May 2019: She began receiving FRONTLINE PLUS DOG 5-22 LBS (S61017) one dose applied topically between the shoulders. Apr 2019*: The owner found two live ticks on unknown dates. 10 Jun 2019: The owner found a live tick on her face during bathing with a pet approved shampoo. She gets groomed approximately once every eight weeks. She has not presented to the veterinary clinic. No treatments have been performed. Her current condition is ongoing. There is one other canine in the household which is also on FRONTLINE PLUS that has not had any ticks. The environment that the canine frequents is unknown. No further medical information expected.
17-Jun-2019	UAE; 19US034683; NY; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 Month(s) **Weight:** 8 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	11-Jun-2019	15-Jun-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the pet owner reported the following event for Ruger, a 12 month old, 8 pound*, neutered male, Domestic Longhair. Unknown date: An unknown quantity FRONTLINE PLUS CATS (S40815BW) were purchased from a local retailer. 11 Jun 2019: The reporter's daughter applied one vial of FRONTLINE PLUS CATS topically between the shoulder blades. It's unknown if Ruger has previously received this product. 15 Jun 2019: The reporter's daughter found an attached, engorged, living tick on Ruger. The species of tick is unknown and since manually removing it from Ruger, it's been thrown away. There is a second cat in the home that also received FRONTLINE PLUS CATS. There is also a dog in the home who will be starting to receive NEXGARD. Although Ruger and the other cat are kept

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											indoors, the do occasionally escape outdoors where they have access to a wooded environment. It can't be confirmed if or when he may have escaped outside prior to finding the tick on his body. No further medical information expected.
17-Jun-2019	UAE; 19US034705; NY; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **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	15-May-2019	01-Jun-2019	17 Day(s)	D-D	Suspected Lack of Efficacy: On 17 Jun 2019, the pet owner reported the following event for Gracie, a 7 year old, 75 pound, spayed female Labrador Retriever. 15 May 2019: One dose of FRONTLINE PLUS DOG 45-88 LBS (R60601BR) was applied topically between the shoulder blades by the animal owner. 1 Jun 2019: The owner observed 3 live ticks on the dog and 3 ticks in the home near where the dog sleeps. Per the owner, the dog has received FRONTLINE PLUS monthly since she was a puppy. There is one other dog in the home, Gracie, who also receives monthly FRONTLINE PLUS and who also experienced a similar reaction, see case 19US034719. Both dogs spend time outside in the yard and were not bathed within 24 hours of application. No further medical information expected.
17-Jun-2019	UAE; 19US034719; NY; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 71 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-May-2019	01-Jun-2019	17 Day(s)	D-D	Suspected Lack of Efficacy: On 17 Jun 2019, the pet owner reported the following event for Maggie, a 13 year old, 71 pound, spayed female Labrador Retriever. 15 May 2019: One dose of FRONTLINE PLUS DOG 45-88 LBS (R60601BR) was applied topically between the shoulder blades by the animal owner. 1 Jun 2019: The owner observed 3 live ticks on the dog and 3 ticks in the home near where the dog sleeps. Per the owner, the dog has been receiving monthly doses of FRONTLINE PLUS since she was a puppy. There is one other dog in the home, Gracie, who also receives monthly FRONTLINE PLUS and who also experienced a similar reaction, see case 19US034705. Both dogs spend time outside in the yard and were not bathed within 24 hours of application. No further medical information expected.
17-Jun-2019	UAE; 19US034735; NC; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 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 product used ok?:** Yes	30-Apr-2019	02-Jun-2019	3 Day(s)	D-D	Suspected Adverse Event: On 17 June 2019, the owner reported the following event for Finn, a 2 year old, 12 pound, neutered Domestic Mediumhair. 30 April 2019: One vial of FRONTLINE PLUS CATS (S41404AW) was applied topically to the skin between the shoulder blades. 3 May 2019: The cat developed hair loss and a scab at the application site. The cat was not seen by the vet and eventually the sore started to look better but the hair was still missing. 30 May 2019: The cat received another application of FL. 2 June 2019: The cat had the same reaction. The cat's symptoms are still ongoing and he has not been seen by the vet. The cat is not on any other mediations, doesn't have any medical conditions, and is in good health. No further information available.
17-Jun-2019	UAE; 19US034742; ID; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** 72 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	26-May-2019	06-Jun-2019*	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the pet owner reported the following event for Reef, a 4 year old, 72 pound, intact male Golden Retriever. 26 May 2019: A single dose of FRONTLINE PLUS DOG 45-88 LBS was applied topically between the shoulder blades by the animal owner. 6 Jun 2019*: The owner found 3 live ticks on the dog; one of which

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						products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					was embedded and engorged. Per the owner, the dog has received FRONTLINE PLUS monthly since he was a puppy. There are no other dogs in the home. The dog spends the majority of his day outside on a wooded property and often swims in a lake, although the owner explicitly shared that the dog does not swim within 24 hours of FRONTLINE PLUS application. NO further medical information expected.
17-Jun-2019	UAE; 19US034744; CA; U.S.A	**Species:** Canine **Breed:** Spaniel (English Springer) **Sex:** U **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 46 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-Jun-2019*	17-Jun-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 17 Jun 2019 the pet owner reported the following event for an unknown 4 year old, 46 pound, Spaniel (English Springer). All other signalments are unknown. *17 Jun 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (UNKNOWN) to the skin between the shoulder blades. It is unknown if this was the first application as the owner refused to provide additional information. Almost immediately after applying the FRONTLINE the dog began running wildly and rubbing application site on everything. The dog has not presented to the vet clinic. It is unknown if the symptoms are ongoing. The dog has a similar reaction to an unknown ear cleaner as well. No further medical information expected.
17-Jun-2019	UAE; 19US034754; CA; U.S.A	**Species:** Feline **Breed:** Maine Coon Cat **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	06-Jun-2019	06-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event/Lack of Efficacy Claim: On 17 Jun 2019, an owner reported the following event for Hermes, a 13 pound*, 7 year old*, neutered male, Maine Coon cat. 2016*: Cat started receiving FRONTLINE PLUS FOR CATS (lot unknown) monthly. 07 Apr 2019: The owner administered one complete vial of FRONTLINE PLUS FOR CATS (lot unknown) between the shoulder blades. No fleas seen at time of administration. 07 May 2019: The owner administered one complete vial of FRONTLINE PLUS FOR CATS (S40815BW) between the shoulder blades. No fleas seen at time of administration. 06 Jun 2019: The owner administered one complete vial of FRONTLINE PLUS FOR CATS (S40815BW) between the shoulder blades. Owner began to see 1-2 fleas on cat. The pet owner received one flea bite. 10 Jun 2019*: Owner noted possible weight loss and irregular eating habits. The cat is the only animal in the home. The cat also goes outside. The cat was in good health at the time of application and is not receiving other medications. No further medical information expected. UPDATE 20 Jun 2019: Per the owner, she applied another dose of FRONTLINE PLUS FOR CATS on 17 Jun 2019 and was still seeing fleas after the application. No further medical information expected. UPDATE 24 Jun 2019: Current status of cat is unknown. No further medical information expected.
17-Jun-2019	UAE; 19US034764; PA; 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 /	01-Feb-2019*	01-Mar-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019 the pet owner reported the following event for 7 felines of unknown signalment. 1 Sep 2018*: All 7 felines started on FRONTLINE PLUS CATS (lot and expiration unknown), 1 vial, topically, at the base of the skull, once monthly. 1 Mar 2019*: The pet owner began seeing fleas inside the home. 1 Jun 2019: The most recent dose was applied to all 7 of the felines. 17 Jun 2019: The pet owner reported he is still seeing a large

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						Cutaneous **Was the product used ok?:** Yes					number of fleas on all 7 of the felines. All 7 of the felines have access to the inside of the home only. There is one other feline inside the home that has fleas and is being treated with FRONTLINE PLUS CATS (see case number 19US034629). No further medical information is expected.
17-Jun-2019	UAE; 19US034773; TX; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 22 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	28-Feb-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the owner reported the following event for Tangerine , 9 year old, 22 pound, neutered male, Domestic Shorthair Feline. 27 Feb 2019: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. 28 Feb 2019: The owner started to notice a small number of fleas on the cat. No fleas were noted in the household. 28 Mar 2019, 28 Apr 2019, and 27 May 2019: Another vial was applied. The owner continued to find 1-2 fleas on the pet sporadically. 17 Jun 2019: The flea issue is still ongoing. The cat is strictly indoor. The cat has been receiving the product since 27 Oct 2019* with no prior issue. There are no other pets in the household.No further medical information is expected.
17-Jun-2019	UAE; 19US034830; -; U.S.A	**Species:** Canine **Breed:** Siberian Husky **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	17-May-2019*	15-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019 a pet owner reported the following event for a Siberian Husky of unknown other signalment. May 2019* and 17 Jun 2019: Owner applied FRONTLINE PLUS (unsubstantiated) (lot unknown) in an unknown manner to the dog. 15 Jun 2019: Owner saw fleas on the dog and tapeworm segments in the stool. Owner bathed the dog with a flea shampoo. Owner has one other dog and unknown number of cats. It is unknown if those pets are also treated with FRONTLINE PLUS. The dog has not been to the clinic or treated for the tapeworms. Owner has sprayed the house for fleas and washed the dog beds. It is unknown if the dog had fleas prior to applying FRONTLINE PLUS. There are no further details about this event as the caller was speaking erratically, would not stop talking to allow me ask questions, and eventually abruptly ended the call. No further medical information expected.
17-Jun-2019	UAE; 19US034849; MO; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Hartz puppy shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-May-2019*	11-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the pet owner reported the following event for Charlie a male neutered, 8 pound, 10 year old, Maltese 21 May 2019: The pet owner noticed 6* fleas and saw 2 dead unattached ticks, and 4 alive unattached ticks. 10 Jun 2018*-10 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S62502AW) topically to skin between the shoulder blades of Charlie monthly on seasonal basis. 3 Jun 2019: The pet owner bathed the dog with Hartz puppy shampoo. 11 Jun 2019: The pet owner continued to see 6* fleas and at least 2 attached alive ticks on the dog. Charlie was in good health at time of application. Charlie was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. Charlie has no history of skin problems or any other issues with topical treatments. Charlie has not had flea problem before in the past. Charlie has not received any other medications or topical treatments. Charlie is indoors and outside for walks. The current status of Charlie is unknown. No further medical 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
17-Jun-2019	UAE; 19US034867; OH; 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	05-May-2019	03-Jun-2019*	29 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019 the pet owner reported the following event for a German Shepherd of unknown further signalment. 5 May 2019: The pet owner applied FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown), 1 dose topically, intrascapular for the first time. There were no fleas noted on the canine or in the environment at the time of application. 3 Jun 2019*: The pet owner began seeing an unknown number of fleas on the canine. 5 Jun 2019*: The most recent dose was applied. 17 Jun 2019: The pet owner reports she is still seeing an unknown number of fleas on the canine but none in the environment. The canine spends the majority of the time inside the home and has access to the lawn with no wooded area. The pet owner reported 2 other cases for other pets in the home (see case numbers 19US034965 and 19US034969). No further medical information is expected.
17-Jun-2019	UAE; 19US034876; TX; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 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?:** Yes	20-Jan-2019	21-Jan-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, Animal owner reported the following event for her two 3 year old, male neutered domestic shorthaired cats. 20 Jan 2017: Started monthly FRONTLINE PLUS CATS (Lot: S40503AX) topically between the shoulder blades. Jan 2019: One cat got out of the house for 2 hours and came back with fleas. 22 Feb 2019 - 22 May 2019: The pet owner is still seeing live fleas on both cats. The pet owner stated the fleas are big and small. Both cats are indoor only cats. There are no other animals in the house. The pet owner bathes both cats but it unknown when and how often. The environment has not been treated. No further information expected.
17-Jun-2019	UAE; 19US034898; -; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** F **Sex qualifier:** - **Age:** 2.00 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	14-Jun-2019*	17-Jun-2019	3 Day(s)	D-D	Suspected Adverse Event: On 17 Jun 2019, a nanny reported the following event for Violet, an approximately 2 year old, 45 pound, intact female Australian Shepherd. 14 Jun 2019*: The owner applied FRONTLINE (product unsubstantiated)(lot unknown) topically between the shoulder blades. 17 Jun 2019: The nanny noticed a large scab with blood and pus that started near the collar and went down to the shoulder blades, the skin is red and irritated. The veterinarian recommended giving a bath, cleaning the area and applying Neosporin. No further medical information expected.
14-Jun-2019	UAE; 19US034915; FL; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** - **Age:** 3.00 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**	01-Mar-2019*	14-Jun-2019*	13 Day(s)	D-C	Suspected Lack of Efficacy/Adverse reaction Claim: On 14 Jun 2019, the pet owner reported to SafetyCall International (SCI) the following event for Beans, a 3 year old*, 16 pound, intact male mixed breed canine. Unknown date, years ago: The dog began receiving FRONTLINE PLUS DOG (unsubstantiated) (lot unknown) monthly with unknown purchase history. It is unknown how the product was applied. Mar 2019* through Jun 2019*: The owner has continued to notice fleas. The dog's excursion history is unknown. The dog has been scratching himself raw to the point he makes himself bleed. He has severe hair loss as well. The pet owner states that she has bathed the dog weekly with a mixture of baby shampoo and dish soap to help kill the fleas.

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						ok?: Unknown to Company					Unknown date: The dog presented to the vet for his ulcerated skin. The dog was diagnosed with anemia, secondary to persistent fleas. It is unknown what other diagnostics were performed. Treatments was provided with Curoxin ointment . 14 Jun 2019: The dog's current condition is ongoing. There a total of 5 canines and 1 felines in the report, but it is unknown how many animals are in the household. See related cases 19US034918, 19US035690, 19US035694, 19US035695, and 19US035698. No further medical information expected.
17-Jun-2019	UAE; 19US034918; FL; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** - **Age:** 3.00 Year(s) **Weight:** 6 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-Mar-2019*	01-Jun-2019*	31 Day(s)	D-A	Suspected Lack of Efficacy Claim: On 14 Jun 2019, the pet owner reported to SafetyCall International (SCI) the following event for Logan, a 3 year old*, 6 pound, intact male Shih Tzu. Unknown date, years ago: The dog began receiving FRONTLINE PLUS FOR DOGS (unsubstantiated) (lot unknown) monthly with unknown purchase history. It is unknown how the product was applied. Mar 2019* through May 2019*: The owner has continued to notice fleas. The dog's excursion history is unknown. The pet owner states that she has bathed the dog monthly with a mixture of baby shampoo and dish soap to help kill the fleas. Unknown date: The dog presented to the veterinary clinic. The dog was diagnosed with anemia, secondary to persistent fleas. It is unknown what other diagnostics were performed or if treatments were provided. The veterinarian had advised a transfusion, but that could not be pursued. 1 Jun 2019*: The dog passed away. There a total of 4 canines and 1 felines in the report, but it is unknown how many animals are in the household. See related cases 19US034915, 19US035690, 19US035694, 19US035695, and 19US035698. No further medical information expected.
17-Jun-2019	UAE; 19US034922; CA; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Yellow) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 107 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Flea Shampoo; Natural Topical product; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-May-2019	04-Jun-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019 the pet owner reported the following event Dane a 10 year old, 107 pound, male neutered Retriever (Labrador, Yellow). *22 May 2014: The owner applied 1 vial of FRONTLINE PLUS DOG 89-132 LBS (S62504AX) to the skin between the shoulder blades for the first time and repeated on a monthly and year round basis. 22 May 2019: The most recent dose was applied. *4 Jun 2019: The owner began noticing a lot of fleas on the dog. There 3 indoor only cats that are on the FRONTLINE PLUS product since August with case number 19US035194. The Owner is not noticing any indoor flea activity. The dog goes for walks through the neighborhood each day. The dog gets regular flea baths on an unknown date at an unknown frequency. The owner is using a natural topical product on the dog on an unknown date at an unknown frequency. The dog does not have a skin condition. Owner has sprayed the yard with an unknown spray and treated everything inside the home at an unknown time. No further medical information expected.
17-Jun-2019	UAE; 19US034923; MD; U.S.A	**Species:** Canine **Breed:** American Bully **Sex:** F **Sex qualifier:** Neutered **Age:** 1.50 Year(s)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	12-Jun-2019	13-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 17 June 2019, the owner reported the following event for Precious, 1.5 years old,80 pounds ,Non-pregnant lactating , American Bully. 12 June 2019: One vial of FRONTLINE PLUS 45-88 LBS (S62408AX) was applied between the shoulder blades, by the pet owner 13 June 2019: The dog started to extremely itch.

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		Weight: 80 lbs				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					14 June 2019: The dog's fur started to fall out in areas that were not close the application site. 15 June 2019: The pet owner bathed the dog with an unknown shampoo. There is 1 other dog in the home on the FRONTLINE PLUS as well with case 19US034926. No further medical information is expected.
17-Jun-2019	UAE; 19US034926; MD; U.S.A	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 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 product used ok?:** Yes	12-Jun-2019	13-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 17 June 2019, the owner reported the following event for Chance, 4 years old, 30 pounds, neutered male, Terrier(Jack Russell)/Chihuahua crossbred. 12 June 2019: One vial of FRONTLINE PLUS 23-44 LBS (S60713X) was applied between the shoulder blades, by the pet owner 13 June 2019: The dog started to extremely itch. 15 June 2019: The pet owner bathed the dog with an unknown shampoo. There is 1 other dog in the home on the FRONTLINE PLUS as well with case 19US034923. No further medical information is expected.
18-Jun-2019	UAE; 19US034944; NJ; U.S.A	**Species:** Canine **Breed:** Collie **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-Jun-2019*	15-Jun-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Jun 2019 a clinic staff reported the following event for a Collie of unknown other signalment. Unknown Date: Owner applied FRONTLINE PLUS (unsubstantiated) (lot unknown) to the dog in an unknown manner. Unknown Date: Owner saw an unknown number of ticks on the dog. It is unknown if the ticks were attached. It is unknown if there are other animals in the home. The reporter has no further details. No further medical information expected.
18-Jun-2019	UAE; 19US034947; GA; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 15 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** pantene shampoo; IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Mar-2019*	17-Jun-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Jun 2019, the pet owner reported the following event for Buddy a male neutered, 15 pound, 9 year old, Small crossbred. Unknown date: The dog takes unknown HEARTGARD (lot number unknown, expiration unknown) (Product unsubstantiated) 1 chew, PO. 9 Mar 2019*: Buddy started FRONTLINE PLUS DOG 5-22 LBS topically to skin between the shoulder blades of Buddy on monthly basis. 6 Jun 2019: The pet owner bathed dog with Pantene Shampoo. 9 Jun 2019: The pet owner applied the most recent dose of FRONTLINE PLUS DOG 5-22 LBS (S61017AL) 17 Jun 2019: The pet owner noticed 15+ fleas on the body of Buddy. The dog was presented to the veterinarian and prescribed unknown chewable. Buddy was in good health at time of application. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. Buddy has no history of skin problems or any other issues with topical treatments. Buddy has not had flea problem before in the past. Buddy has not received any other topical treatments. Buddy is indoors and outside for walks. The current status of Buddy is unknown. No further medical information.

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18-Jun-2019	UAE; 19US034963; 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?:** Unknown to Company	18-Jun-2019	18-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 18 Jun 2019, the pet owner reported the following event for a canine with unknown signalment. 18 Jun 2019: The dog received FRONTLINE PLUS DOG (unsubstantiated) (S61101AR) for the first time, applied topically on the side of one of the shoulders. Approximately 3 hours later, the dog still had a oily spot at the application site. The dog's current condition is ongoing. The dog has not presented to the veterinary clinic. No further medical information expected.
18-Jun-2019	UAE; 19US034964; -; 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-Apr-2019*	05-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 18 Jun 2019, Animal owner reported the following event for her dog. *01 Apr 2019: The pet owner found 2 ticks crawling on the dog. She applied the entire contents of 1 vial of FRONTLINE PLUS DOG 0-22 LBS (lot unknown) topically in an unknown location. The pet owner stated she did not remove the ticks but watched them to see if they died within 24-48 hours. The pet owner noted 4 days post application, the ticks were still alive. *01 May 2019 and *01 Jun 2019: The pet owner applied the product and the pet owner was still seeing ticks crawling on her dog. The ticks were not removed and the owner tried using a comb to remove them. All additional information unknown.
18-Jun-2019	UAE; 19US034965; 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	05-May-2019	03-Jun-2019	29 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019 the pet owner reported the following event for 3 felines of unknown signalment. 5 May 2019: The pet owner applied FRONTLINE PLUS CATS (lot and expiration unknown), 1 dose topically, intrascapular for the first time. There were no fleas noted on the feline or in the environment at the time of application. 3 Jun 2019*: The pet owner began seeing an unknown number of fleas on all 3 felines. 5 Jun 2019*: The most recent dose was applied to all 3 felines. 17 Jun 2019: The pet owner reports she is still seeing an unknown number of fleas on all 3 felines but none in the environment. The 3 felines spends all of the time inside the home or on the enclosed porch. The pet owner reported 2 other cases for other pets in the home (see case numbers 19US034867 and 19US034969). No further medical information is expected.
18-Jun-2019	UAE; 19US034969; OH; U.S.A	**Species:** Canine **Breed:** Chihuahua **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	05-May-2019	03-Jun-2019*	29 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019 the pet owner reported the following event for a Chihuahua of unknown further signalment. 5 May 2019: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown), 1 dose topically, intrascapular for the first time. There were no fleas noted on the canine or in the environment at the time of application. 3 Jun 2019*: The pet owner began seeing an unknown number of fleas on the canine. 5 Jun 2019*: The most recent dose was applied. 17 Jun 2019: The pet owner reports she is still seeing an unknown number of fleas on the canine but none in the environment. The canine spends the majority of the time inside the home and

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						to Company					has access to the lawn with no wooded area. The pet owner reported 2 other cases for other pets in the home (see case numbers 19US034867 and 19US034965). No further medical information is expected.
18-Jun-2019	UAE; 19US034993; AL; U.S.A	**Species:** Canine **Breed:** Dachshund **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 12 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Advantix; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-May-2019	01-Jun-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Jun 2019, a pet owner reported the following event for Charlie, a 14 year old, 12 pound, neutered male Dachshund. 30 May 2019: The dog received 1 application of FRONTLINE PLUS DOG 5-22 LBS (S61203AX) topically between the shoulder blades for the first time. The owner did not notice fleas prior to the application. 1 Jun 2019*: The pet owner noticed a live flea on her leg and is seeing a few live fleas in the home. 18 Jun 2019: The pet owner is seeing about 10 live fleas on the dog. The dog has previously received monthly Advantix without any issues. The yard is not fenced in and there are trees on the property. The dog goes outside on a leash. The dog gets bathed about every 6 weeks and does not have a history of skin issues. The pet owner usually has her yard treated and the last treatment was about 1 month ago. She has not treated the inside of the home yet. There is 1 cat in the household that is also on FRONTLINE and has fleas, see case 19US034999. No further information expected.
18-Jun-2019	UAE; 19US034996; CA; 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	04-Apr-2019	18-Jun-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Jun 2019, Animal owner reported the following event for her dog. 04 Apr 2019: Started monthly FRONTLINE PLUS DOG 5-22 LBS (Lot unknown) topically between the shoulder blades for the first time. 04 May 2019 and 04 Jun 2019: A dose was applied. *18 Jun 2019: The pet owner reports the dog is covered in fleas. The number of fleas is unknown. All additional information unknown. No further information expected.
18-Jun-2019	UAE; 19US034999; AL; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 16 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Advantage; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	30-May-2019	01-Jun-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Jun 2019, a pet owner reported the following event for Gabriel, a 6 year old, 16* pound, neutered male Domestic Longhair. 30 May 2019: The cat received 1 application of FRONTLINE PLUS CATS (S40601AX) topically between the shoulder blades in one spot for the first time. The owner did not notice fleas prior to application. 1 Jun 2019*: The pet owner noticed 5 live fleas on the cat's abdomen and is seeing a few live fleas in the home. 16 Jun 2019*: The pet owner noticed flea dirt under the cat's neck. The cat is indoor only and has previously been on monthly, year round Advantage without any issues. There is 1 dog in the home that is also on FRONTLINE and has fleas, see case 19US034493. No further information expected.
18-Jun-2019	UAE; 19US035004; NM; U.S.A	**Species:** Feline **Breed:** Domestic Longhair	1	1	0	**Product used:** FIPRONIL 10%/S	17-Jun-2019	18-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 18 Jun 2019, the veterinarian reported the following event for Oscar, a 1 year old, 10.5 pound, neutered male Domestic Longhair.

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		(Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 10.5 lbs				METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					17 Jun 2019: The cat received 1 dose of FRONTLINE PLUS FOR CATS (lot and expiration unknown) applied topically between the shoulder blades by the animal owners. Within 12 hours, the owners observed the cat licking the application site. 18 Jun 2019: The cat began vomiting a pink tinged liquid within 24 hours of FRONTLINE PLUS ingestion, he presented to the clinic but no treatments have been performed at this time. Per the veterinarian, the cat has a history of eating human food and may have ingested salted pork on the night of FRONTLINE PLUS ingestion. No further medical information expected. UPDATE 18 Jun 2019: Per veterinarian, the pet also exhibited anorexia at the time of the report. No further medical information expected.
18-Jun-2019	UAE; 19US035030; TX; U.S.A	**Species:** Feline **Breed:** American Shorthair **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 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-Jun-2019	02-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019 the pet owner reported the following event for Be Be a 9 year old, 18 pound, female spayed American Shorthair cat. *2016: The owner applied 1 vial of FRONTLINE PLUS CATS (UNKNOWN) to the skin between the shoulder blades for the first time and repeated on a monthly and seasonal basis. Owner starts applying in Apr of each year and discontinues in the Winter . *15 Apr 2019: The first dose of the season was applied. 1 Jun 2019: The most recent dose was applied a couple weeks late because she was noticing flea dirt. 2 Jun 2019: The owner continued noticing flea dirt and saw 1 flea on the cat. There are no other pets in the home. The Owner is not noticing any indoor flea activity. The cat is indoor/outdoor. The cat does not have a skin condition but has thin fur. The cat does not get regular baths. The cat has a history of flea allergy dermatitis and regularly chews on paws. No further medical information expected.
18-Jun-2019	UAE; 19US035041; CA; U.S.A	**Species:** Canine **Breed:** Australian Sheep Dog **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 70 - 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	03-Apr-2019	18-Jun-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Jun 2019, the pet owner reported the following event for Happy, a 7 year, 70-80 pound*, female spayed, Australian Sheep Dog. 3 Apr 2019: She was not having an issue with fleas. The owner purchased an 8 pack of FRONTLINE PLUS DOG 45-88 LBS (S60809AX) and applied 1 vial to the dog in one area between the should blades for the first time ever. 6 May 2019: 1 vial was applied to the dog. 6 Jun 2019: 1 vial was applied to the dog. 18 Jun 2019: The owner saw 10 fleas on the dog. The owner treats seasonally with different products . The dog goes outside for potty breaks and recreation where there are gophers present. There have been fleas in the home previously, none are biting humans at the moment. The dog was bathed before the application of FRONTLINE at the groomer with an unknown shampoo. The dog has a history of dry skin. No further medical information is expected.
15-Jun-2019	UAE; 19US035072; -; 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	N/A	15-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 15 Jun 2019, the following information was received via email by the pet owner for a female, canine of further unknown signalment. Unknown dates: The canine received unknown FRONTLINE PLUS DOG (lot unknown) (product unsubstantiated). The doses, routes, and location of product administration are unknown as the information was not provided in the email by the reporter. On unknown dates since April 2019*, the pet owner has manually removed 13 ticks from the canine. No information regarding 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
						Was the product used ok?: Unknown to Company					species and/or condition of the ticks were provided and the canine did not have any ticks prior to her first unknown FRONTLINE PLUS DOG application. Presently, her status is unknown. No further medical information expected.
18-Jun-2019	UAE; 19US035078; CA; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** - **Age:** - **Weight:** 5 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	11-Jun-2019*	18-Jun-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Jun 2019 the pet owner reported the following event for a 5 pound Chihuahua of unknown further signalment. 1 Jun 2018*: Started on FRONTLINE PLUS DOG 5-22 LBS (product unsubstantiated) (lot and expiration unknown), unknown volume, route, or application site once monthly. 11 Jun 2019*: The most recent dose was applied. 18 Jun 2019: The pet owner began to see an unknown number of fleas inside the home and on the canine. It is unknown where the canine spends the majority of the time or what outside areas they have access to. There are no other pets in the household. No further medical information is expected.
18-Jun-2019	UAE; 19US035091; TX; 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	14-Jun-2019	18-Jun-2019	4 Day(s)	D-D	Suspected Lack of Efficacy/ Adverse reaction Claim: On 18 Jun 2019, Animal owner reported the following event for his 3 cats. 12 Jun 2019: The pet owner notice a heavy flea burden on his 3 indoor cats. He bathed all three cats with a flea shampoo. Pet owner noted hundreds of fleas were coming off from bathing . 14 Jun 2019: The pet owner purchased a 3 pack of FRONTLINE PLUS CATS (Lot unknown) and applied the full contents topically between the shoulder blades of his 3 cats. 18 Jun 2019: The pet owner reported his cats are scratching. The pet owner has not seen fleas on his cats but assumes the scratching is from fleas. There are no other animals in the home and the cats are indoor only cats. The pet owner has not treated his environment. No further information expected.
18-Jun-2019	UAE; 19US035093; TX; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** - **Weight:** 15 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	23-May-2019	26-May-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 4 Jun 2019, the pet owner reported the following event for Ella, a female spayed, 15 pound, Chihuahua, other signalment unknown. 23 May 2019: The pet owner bathed the dog with Dawn dish soap. The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S62502AW) topically to skin between the shoulder blades of the dog for the first time. 26 May 2019: The pet owner first noticed 15+ fleas on both of the dog. 4 Jun 2019: The dog was in good health at time of application. The dog was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen any fleas in the home. The dog has no history of skin problems or any other issues with topical treatments. The dog has not had flea problem before in the past. The dog has not received any other medications or topical treatments. The dog has not been bathed. The dog is indoors and outside for walks. The current status of the dog is unknown. Ella shares home with one other dog that is treated with FRONTLINE PLUS DOG 23-44 LBS (S61009AL) with case number 19US031427. No further medical information.
18-Jun-2019	UAE; 19US035094; OR; U.S.A	**Species:** Canine **Breed:** Poodle (Miniature)	1	1	0	**Product used:** FIPRONIL 10%/S	26-Mar-2019	13-Jun-2019	11 Week(s) 2 Day(s)	D-C	Suspected Adverse Event: On 18 Jun 2019, the owner reported the following event for Eddie, a 9 year old, 15 pound, male, neutered, Miniature Poodle.

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		Sex: M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 15.0 lbs				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					26 Mar 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (M62914AL) was applied in-between the shoulder blades by the pet owner. 13 Jun 2019: The pet had a seizure. The pet fell over and convulsed for about 30 seconds and came too quickly. The dog was presented to the vet, a CBC/CHEM panel was ran with inconclusive results. The vet suggested to monitor only. 18 Jun 2019: The dog has recovered. The pet has been on FRONTLTINE off and on seasonal for the past year (since 2018*). The March 2019 dose is the only reported dose given in 2019. No further medical information is expected at this time.
18-Jun-2019	UAE; 19US035146; CA; U.S.A	**Species:** Canine **Breed:** Cavalier King Charles **Sex:** F **Sex qualifier:** Lactating **Age:** 2.00 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 (Indication not indicated / recommended)	17-Jun-2019	18-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 18 Jun 2019, a pet owner reported the following event for Annabell , a 2 year old, 25 pound, female King Charles Cavalier. 14 Jun 2019*: The dog gave birth to an unknown amount of puppies. 17 Jun 2019: The dog received 1 application of FRONTLINE PLUS DOG 23-44 LBS (S62308AW) topically between the shoulder blades for the first time this year. The owner was seeing a few live fleas on the dog prior to application. 18 Jun 2019: The pet owner is seeing 1-2 live fleas on the puppies' faces. The pet owner is not seeing any fleas currently on the mother. The pet owner has used FRONTLINE in the past during summer months since 2018* without any adverse events. No further medical information expected.
17-Jun-2019	UAE; 19US035194; CA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 7 - 11 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Unknown flea shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	22-Aug-2018*	04-Jun-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019 the pet owner reported the following event for 3 unknown 7-11 pound felines. All other signalments are unknown *22 Aug 2018: The owner applied 1 vial of FRONTLINE PLUS CATS (UNKNOWN) to the skin between the shoulder blades for the first time and repeated on a monthly and year round basis. 22 May 2019: The most recent dose was applied. *4 Jun 2019: The owner began noticing a lot of fleas on the cats. There is 1 dog that is on the FRONTLINE PLUS product since 2014 with case number 19US034922. The Owner is not noticing any indoor flea activity. The cats are indoor only. The cat gets regular flea baths on an unknown date at an unknown frequency. The cats do not have a skin condition. Owner has sprayed the yard with an unknown spray and treated everything inside the home at an unknown time. No further medical information expected.
27-Jun-2019	UAE; 19US035237; VA; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** - **Age:** 5.00 Year(s) **Weight:** 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	16-Apr-2019	16-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 18 Jun 2019, a pet owner reported the following event for Sunshine, a 5 pound, 5 year old, intact female, Chihuahua. 16 Apr 2019: The dog started for the first time on monthly FRONTLINE PLUS DOG 5-22 LBS (S6107AL), with 1 dose applied topically between the shoulder blades. The pet owner was already seeing a large amount of fleas on her dog. The dog is mostly indoor but she does go outside to the front yard for potty breaks. This is the only pet in the home. 16 Jun 2019: The pet owner is still seeing a large amount of fleas on her dog. She is not seeing fleas inside of the home only on the dog. The owner has discontinued the use of the product due to the lack of efficacy. No further medical information expected.

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18-Jun-2019	UAE; 19US035241; WA; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 3 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	28-Jan-2019	29-Jan-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 18 Jun 2019, the owner reported the following event for Precious, 14 year old, 3.6 pound, spayed female, Yorkshire Terrier canine. 28 Jan 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (P62719BL) was applied between the shoulder blades. Unknown date: The dog experienced hair loss at the application site. The dog also had waxy skin around the ear. The pet presented to the clinic on another unknown date. The owner bathed the pet and applied neosporin. 18 Jun 2019: The symptoms have improved but the hair loss is still present. The dog has received the product seasonally since 2005* with no issue. There are 2 other dogs in the household, one of the dogs also received the product and experienced no symptoms. No further medical information is expected.
14-Jun-2019	UAE; 19US035257; CA; 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-Dec-2018*	17-Dec-2018*	N/A	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, a pet owner reported the following event for a feline of unknown signalment. 10 Dec 2018*: The cat began receiving monthly FRONTLINE PLUS CATS (S41003AW) topically between the shoulder blades because the pet owner was seeing fleas on the cat. 17 Dec 2018*: The pet owner noticed a couple of live fleas on the cat. 27 May 2019: The most recent dose of FRONTLINE was applied. The pet owner stated that she has continued to see 1-2 live fleas after each application since Dec 2018 and over the past few weeks has seen 10 live fleas on the cat. She is concerned that this is a bad batch of FRONTLINE that she purchased from Chewy. There is 1 other cat in the home that also has fleas and is on FRONTLINE, see case 19US034258. There are 2 dogs in the home, 1 is on FRONTLINE and 1 is on Bravecto. The pet owner is not noticing fleas on the dogs. No further information expected.
19-Jun-2019	UAE; 19US035278; GA; U.S.A	**Species:** Canine **Breed:** Boxer **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 60.000 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	18-Jun-2019	18-Jun-2019	0 Day(s)	D-B	Suspected Adverse Event: On 19 Jun 2019, the pet owner reported the following event for Phoenix, a male neutered, 60 pound, 7 year old, Boxer mix. Unknown dates: The pet owner has used unknown amount FRONTLINE PLUS DOG (lot number unknown) previously on seasonal basis. 18 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (S61202AX) topically to skin between the shoulder blades of Phoenix for the first time this year. After approximately a few hours*post application the pet owner noticed Phoenix experience lethargy not wanting to eat and have a seizure that lasted less than 1* minute. The seizure caused him to be unresponsive to pet owner's commands and him to bump into things around the home. 19 Jun 2019: The pet owner noticed Phoenix experience another seizure this morning around 5:30am with him shaking and being unresponsive to her commands and signs of lethargy. Phoenix was in good health at time of application. Phoenix was not presented to veterinarian. Phoenix has not had any other products at the same time as the FRONTLINE PLUS application. Phoenix does not have history of drug or vaccine reactions. Phoenix is currently at home with ongoing issue. No further medical information. UPDATE 19 June 2019: The pet owner brought the dog to vet, the dog is blind in the left eye now, but vet believes that it will resolve

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											in a few days.Performed routine bloodwork, results came back normal normal. The vet instructed the owner to call back if blindness does not go away or if seizures start again. No further medical information. UPDATE 20 Jun 2019: Per owner the dog has not improved. The dog has now refused to drink water. No further medical information.
19-Jun-2019	UAE; 19US035287; TX; U.S.A	**Species:** Canine **Breed:** Pekingese **Sex:** M **Sex qualifier:** Neutered **Age:** 13.00 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	01-Jun-2019	18-Jun-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 19 June 2019, the owner reported the following event for Kirby, a 35 pound, 13 year old, neutered male Pekingese. 1 June 2019: The owner noticed the dog itching and applied one vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown). 18 June 2019: The owner noticed a large number of fleas on the dog and the dog itching. Another application of FL was given. The dog has been on FL year round all his life and has been having ongoing flea issues for the past month. The dog is exposed to the outdoor environment daily for walks and potty breaks. The dog is not bathe often. The owner isn't sure if there's an infestation in the home or not. There is one outdoor cat that is treated with another flea mediation. No further information available.
19-Jun-2019	UAE; 19US035341; NC; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **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:** unknown whitening shampoo; unknown oatmeal conditioner; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-May-2019*	20-May-2019*	N/A	D-D	Suspected Adverse Event: On 19 Jun 2019, the pet owner reported the following event for Charlie, a 5 year old, 13 pound, neutered male, Shih Tzu. Unknown dates: The canine was bathed with an unknown whitening shampoo and oatmeal conditioner. May 2019*: The reporter first observed an unknown number of fleas on him. 19 May 2019*: She applied one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) topically between the shoulder blades for the first time. Unknown dates: Following product application, Charlie became mildly pruritic. The reporter could not recall the duration to symptom onset. 18 Jun 2019: Charlie was bathed in the same unknown whitening shampoo and oatmeal conditioner. After he was dry later that night, she applied one vial of FRONTLINE PLUS DOG 5-22 LBS topically between the shoulder blades for the second time. Within two hours of product application, his pruritus worsened and she also observed him have a 'sudden burst of energy'. She did not observe any fleas at the time of application. 19 Jun 2019: No treatment has been given despite the ongoing symptoms. Likewise, no fleas are seen on Charlie. No further medical information expected.
17-Jun-2019	UAE; 19US035376; IL; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various **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	10-Jun-2019	17-Jun-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the pet owner reported the following event for 2 canines with unknown signalment. 10 Jun 2019: The dogs began receiving FRONTLINE PLUS FOR DOGS 45-88 LBS (S62202AX) every 3 weeks with a 3 pack purchased from Amazon on an unknown date. Fleas were seen on the dogs prior to product application. 30 Apr 2019*: A dose was applied to both dogs on the skin between the shoulders. 21 May 2019*: A dose was applied to both dogs on the skin between the shoulders. 10 Jun 2019: A dose was applied to both dogs on the skin between the shoulders.

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						(Treatment / vaccination program not respected)					17 Jun 2019*: The owner noticed a severe amount of fleas on both dogs. The dogs do live on a large property in the country. It is unknown if the dogs presented to the veterinary clinic. The condition of both dogs is ongoing. There a total of 2 canines and 15 felines in the household. There are two related cases, see 19US034584 and 19US035353. No further medical information expected.
19-Jun-2019	UAE; 19US035384; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **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?:** Yes	17-Jun-2019*	19-Jun-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 19 Jun 2019, the pet owner reported the following event for a 9 pound*, female, indoor only feline of further unknown signalment. 27 May 2019*: The reporter's roommate's dog who weighs 20 pounds was introduced into the home. Upon introduction into the home, the canine had fleas and on approximately the same date, was treated with one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown), applied topically between the shoulder blades. It's unknown if the canine has previously received this product or any other flea/tick control product prior. Unknown date: The reporter purchased an unknown quantity of FRONTLINE PLUS CATS (lot unknown) from a Walmart. 17 Jun 2019: She applied one vial of FRONTLINE PLUS CATS topically between the shoulder blades to the feline. It's unknown if the feline has previously received this product and the reporter did not confirm if fleas were present on the patient prior to product application. 18 Jun 2019: Her roommate felt two fleas on her person which was in close proximity to where the feline had been laying on the roommate's bed. 19 Jun 2019: The reporter is seeing at least twenty fleas on the feline. Presently, she's not finding fleas in the home, on her person, or on the dog and no treatment has been pursued. The canine goes outside in a slightly wooded yard. No further medical information expected.
19-Jun-2019	UAE; 19US035390; -; 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:** unknown shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Jun-2019*	12-Jun-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 19 June 2019, the owner reported the following event for a 70 pound dog (signalment unknown). *4 June 2019: The dog was bathed with an unknown shampoo. *5 June 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (R62309AR) was topically applied to the skin between the shoulder blades for the first time. *12 June 2019: The dog started to pick up fleas. *17 June 2019: The dog was bathed in an unknown shampoo. There are no fleas in the home. The dog is exposed to a grass yard daily and the dog is bathed as needed. No further information available.
19-Jun-2019	UAE; 19US035394; OH; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 98 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	18-Jun-2019	18-Jun-2019	0 Day(s)	D-B	Suspected Adverse Event: On 19 Jun 2019, a pet owner reported the following event for Louie, a 3 year old (born 26 Jul 2015), 98 pound, neutered male Golden Retriever/Standard Poodle mix. 18 Jun 2019: The dog received 1 application of FRONTLINE PLUS DOG 89-132 LBS (S62006BX) topically between the shoulder blades in one spot. Approximately 4-5 hours later the owner heard the dog having a seizure. It is unknown how long it lasted. The owner then saw the dog walk out of the bedroom into the hallway. The dog was weak and ataxic and then fell over on its side and was shaking all over and drooling. This lasted for less than 30

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						Was the product used ok?: Yes					seconds, and then dog seemed disoriented and was shaky and ataxic. He wanted to be close to the owner and seemed nervous. The dog vomited one time about 30 minutes later. The dog did not present to the clinic and no treatments were performed. 19 Jun 2019: The dog was back to normal. The dog has previously been on FRONTLINE seasonally from Apr to Oct since 2016* and has reacted to FRONTLINE in the past, see case 19US038868. No further medical information expected.
19-Jun-2019	UAE; 19US035410; CA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 18.00 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	19-Jun-2019	19-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: 19 Jun 2019: An owner reported the following event in Missy; an indoor-outdoor, 18 year old, 9 pound, spayed, female, Domestic Short hair. 19 May 2019*: The owner administered one vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) topically between the shoulders. No fleas were seen at the time of application. 19 Jun 2019: The owner administered one vial topically between the shoulders. No fleas were seen at the time of application but 2 fleas were seen in the bathroom. There are no other animals in the home. No further medical information expected.
19-Jun-2019	UAE; 19US035439; CA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 15.000 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown flea shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Jun-2019*	06-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 19 June 2019, the owner reported the following event for 15 pounds canine (all other signalments unknown). 5 June 2019*: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades, by the pet owner. 6 June 2019*: The dog had fleas. 12 June 2019*: The dog had a bath in unknown flea shampoo. The owner is not seeing any flea activity in the home. The dog does not have any skin issues. The dog is mostly indoors but does go outside into a yard for bathroom breaks. There is 1 other dog in the home using FRONTLINE PLUS but is not having any issues with fleas. No further medical information is expected.
19-Jun-2019	UAE; 19US035446; MN; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 16 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	19-Jun-2019	19-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 19 June 2019, the owner reported the following event for Bill, a 9 year old, 16 pound, neutered male Domestic Longhair. 19 June 2019: One vial of FRONTLINE PLUS CATS (S40717AW) was topically applied to the skin between the shoulder blades for the first time. Within 10 minutes the cat licked the application site and started to experience hyper salivation and he recovered in 5 minutes. No further information available.
19-Jun-2019	UAE; 19US035461; CA; U.S.A	**Species:** Canine **Breed:** Siberian Husky **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 Year(s)	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** oatmeal	10-Jun-2017*	16-Jun-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 19 Jun 2019, a pet owner reported the following event for Mia, a 12 year old, 68 pound, spayed female Siberian Husky. Unknown Date: The dog started FRONTLINE PLUS DOG 45-88 LBS (R61811AR). 10 JUN 2019: The owner applied 1 dose of FRONTLINE topically on the neck and tail due to thick coat.

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		Weight: 68 lbs				shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					16 Jun 2019: The owner saw a large amount of fleas, did not indicate exact amount. The owner bathes the dog in an oatmeal shampoo. The dog goes inside and outside and has been treated with FRONTLINE year round for years. There is another dog in the house, that received FRONTLINE on the same date that is having the same issue. It is unknown if both canines recovered. No further medical information expected.
19-Jun-2019	UAE; 19US035519; MI; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 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	16-Jun-2019	19-Jun-2019*	3 Day(s)	D-C	Suspected Adverse Event: On 19 Jun 2019, the pet owner reported the following event for Nala a female spayed, 75 pound, 2 year old, Mixed breed. 16 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS(S62204AX) topically to skin between the shoulder blades of Nala for the first time. After unknown period of time post application the pet owner noticed Nala with burn spot on her neck, shoulder, multiple red sores on her body, and hair loss at the application site. Nala was in good health at time of application. Nala was not presented to veterinarian. Nala has not had any other products at the same time as the FRONTLINE PLUS DOG 45-88 LBS (S62204AX) Nala does not have history of drug or vaccine reactions. Nala has not had FRONTLINE prior to reaction. Nala is currently at home with ongoing issue. No further medical information. UPDATE 03 Jul 2019: After further review, corrected the local assessment agency.
19-Jun-2019	UAE; 19US035552; GA; 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 flea shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-May-2019	03-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 19 June 2019, the owner reported the following event for a canine(all other signalments unknown). 2 May 2019: The dog started the FRONTLINE PLUS on a monthly basis. 2 June 2019: The most recent vial of FRONTLINE PLUS DOG 89-132 LBS(lot unknown) was applied between the shoulder blades, by the pet owner. 3 June 2019*: The dog had fleas. The dog was bathed in an unknown flea shampoo on an unknown date. The owner is not seeing any flea activity in the home. It is unknown where the dog frequents on a daily basis. No further medical information is expected.
19-Jun-2019	UAE; 19US035569; WV; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	6	6	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	30-Apr-2019	31-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: 19 Jun 2019: An owner reported the following event in 6 indoor-outdoor dogs of unknown signalment. 31 Mar 2019: The owner administered one vial FRONTLINE PLUS DOGS 23-44 LBS (R60811AL) topically between the shoulders to 6 dogs. 30 Apr 2019: The owner administered one vial topically between the shoulders to 6 dogs. 31 May 2019: The owner administered one vial topically between the shoulders to 6 dogs. Fleas were seen at the time of application. 03 Jun 2019: The owner saw fleas on the dogs. There are no other animals in the home. The environment has been treated by an exterminator and seven dust. No further medical information

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						to Company					expected.
19-Jun-2019	UAE; 19US035599; MI; 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	24-May-2019	19-Jun-2019	26 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 19 Jun 2019 an animal owner reported the following event in her 2 canines. All other signalment unknown. 24 May 2019: The two canines were administered FRONTLINE PLUS DOGS 45-88 LB (lot, expiration unknown) between the shoulder blades. No fleas were seen at time of application. 19 Jun 2019: The animal owner is seeing fleas on both canines. The canine were reported to be itching as well. The canines have been on the FRONTLINE PLUS year round for at least one year. There are no other animals in the home. There are no outdoor animals. Canines have access to outdoors. No further information provided nor expected.
19-Jun-2019	UAE; 19US035622; TX; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 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	18-May-2019	19-Jun-2019	4 Week(s) 4 Day(s)	D-D	Suspected Lack of Efficacy Claim: 19 Jun 2019: An owner reported the following event in Kratos; a 4 year old, 28 pound, neutered, male, medium crossbred, indoor-outdoor dog. 18 Feb 2019: The owner administered one vial FRONTLINE PLUS DOGS 23-44 LBS (S60713AX) topically between the shoulders. No fleas were seen at the time. 18 Mar 2019: The owner administered one vial topically between the shoulders. No fleas were seen at the time. 18 Apr 2019: The owner administered one vial topically between the shoulders. Fleas were seen at the time. 18 May 2019: The owner administered one vial topically between the shoulders. No fleas were seen at the time. 19 Jun 2019: The owner sees 4-5 live fleas. There are no other animals in the home. No further medical information available.
19-Jun-2019	UAE; 19US035642; 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?:** Yes	01-May-2019*	02-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim:On 19 June 2019, the owner reported the following event for 2 cats (all other signalments unknown). Unknown date: The cats started FRONTLINE PLUS on a monthly basis. 1 June 2019*: The most recent vial of FRONTLINE PLUS CATS(lot unknown) was applied between the shoulder blades, by the pet owner. 2 June 2019*: The cats had fleas. It is unknown if the cats get bathed. The owner is not seeing any flea activity in the home. The cats are primarily indoors. No further medical information is expected.
19-Jun-2019	UAE; 19US035659; MO; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 5.000 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Dawn and Vinegar; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Apr-2019	06-May-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 19 Jun 2019 the pet owner reported the following event for an unknown 5-10 pound feline. All other signalments are unknown. 7 Apr 2019: The owner applied 1 vial of FRONTLINE PLUS CATS (UNKNOWN) to the skin between the shoulder blades for the first time. 6 May 2019: The owner began seeing about 20 fleas on the cat each day. The owner began bathing the cat in Dawn and vinegar and repeated baths every other day. 7 May 2019: The owner applied another dose. 8 May 2019: The owner continued see fleas on the cat. 1 Jun 2019: The owner applied the most recent dose. 2 Jun 2019: The owner continued to see about 20 fleas per day. There are 2 dogs in the home being treated with FRONTLINE

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											PLUS with case number 19US026645 and 19US027518. The cat is indoor only. There is no indoor flea activity. The owner is bombing the house every week for an unknown amount of time. No further medical information expected.
19-Jun-2019	UAE; 19US035660; -; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	5	5	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	05-Jun-2019	05-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 19 Jun 2019, the pet owne reported the following event for a female, Pitbull. All signallments unknown because the pet owner was unable to provide the information. Unknown: The dog was seen by the vet and treated for flea allergy dermatitis. 5 Jun 2019: 1 vial of FRONTLINE PLUS DOG 23-44 LBS was applied, it is unknown where the product was applied. The owner has been seeing a large number of fleas on the dog every day since the application. Unknown: The dog was bathed in an unknown flea and tick shampoo from the vet. The dog was not having an issue with fleas prior to FRONTLINE application. There are 4 other dogs in the home having an issue with fleas and were also treated with FRONTLINE. Owner was not able to provide signalments. No further medical information is available.
19-Jun-2019	UAE; 19US035661; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 25 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	05-Jun-2019*	12-Jun-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 19 June 2019, the owner reported the following event for a 25 pound dog (signalment unknown). *4 June 2019: The dog was bathe with an unknown shampoo. *5 June 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (R62301AR) was topically applied to the skin between the shoulder blades for the first time. *12 June 2019: The dog started to pick up fleas. *17 June 2019: The dog was bathe in Dawn due to fleas. There are no fleas in the home. The dog is exposed to a grass yard daily and the dog is bathe as needed. No further information available.
14-Jun-2019	UAE; 19US035690; FL; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 4.6 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-Jun-2019*	14-Jun-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, the pet owner reported to SafetyCall International (SCI) the following event for Lacey, an 8 month old*, 4.6 pound, intact female Domestic Shorthair. Unknown date, years ago: The cat began receiving FRONTLINE PLUS FOR CATS (lot unknown) monthly with unknown purchase history. It is unknown how the product was applied. Mar 2019* through Jun 2019*: The owner has continued to notice fleas. It is unknown if the cat goes outdoors. The cat's excursion history is unknown. The cat has been scratching herself raw to the point she makes himself raw. She has severe hair loss as well. It is unknown if the cat presented to the veterinary clinic. . It is unknown what other diagnostics were performed or if treatments were provided. Her current condition is ongoing. There a total of 4 canines and 1 felines in the report, but it is unknown how many animals are in the household. See related cases 19US034915, 19US034918, 19US035694, 19US035695, and 19US035698. No further medical information expected.
20-Jun-2019	UAE; 19US035693;	**Species:** Canine **Breed:** Large	1	1	0	**Product used:** FIPRONIL	21-May-2019	21-May-2019	0 Day(s)	D-D	Suspected Adverse Event: On 20 Jun 2019, the pet owner reported the following event for Teddy a female spayed , 40 pound,

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	NJ; U.S.A	crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 40 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					1 year old, Large Crossbreed. 21 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 23-44 LBS (P60802AL) topically to skin between the shoulder blades of Teddy for the first time. After approximately 4* hours post application the pet owner noticed Teddy experience lethargy not wanting to eat that lasted 3* days. 24 May 2019*: The dog recovered from lethargy. 8 Jun 2019: Teddy was presented to veterinarian for physical exam. Teddy was in good health at time of application. Teddy has not had any other products at the same time as the FRONTLINE PLUS DOG application. Teddy does not have history of drug or vaccine reactions. Teddy has not had FRONTLINE prior to reaction. Teddy is currently at home recovered. No further medical information.
14-Jun-2019	UAE; 19US035694; FL; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** - **Age:** 7.00 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?:** Unknown to Company	01-Jun-2019*	14-Jun-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, the pet owner reported to SafetyCall International (SCI) the following event for Bull, a 7 year old*, 60 pound, intact male mixed breed canine. Unknown date, years ago: The dog began receiving FRONTLINE PLUS FOR DOGS (unsubstantiated) (lot unknown) monthly with unknown purchase history. It is unknown how the product was applied. Mar 2019* through Jun 2019*: The owner has continued to notice fleas. The dog's excursion history is unknown. The pet owner states that she has bathed the dog monthly with a mixture of baby shampoo and dish soap to help kill the fleas. Unknown date: The dog presented to the veterinary clinic. The dog was diagnosed with anemia, secondary to persistent fleas. It is unknown what other diagnostics were performed. 14 Jun 2019: The dog's current condition is ongoing. There a total of 4 canines and 1 felines in the report, but it is unknown how many animals are in the household. See related cases 19US034915, 19US034918, 19US035690, 19US035695, and 19US035698. No further medical information expected.
14-Jun-2019	UAE; 19US035695; FL; U.S.A	**Species:** Canine **Breed:** Mastiff **Sex:** F **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** 185 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-Jun-2019*	14-Jun-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, the pet owner reported to SafetyCall International (SCI) the following event for Darla, a 4 year old*, 185 pound, intact female Neopolitan Mastiff. Unknown date, years ago: The dog began receiving FRONTLINE PLUS FOR DOGS (unsubstantiated) (lot unknown) monthly with unknown purchase history. It is unknown how the product was applied. Mar 2019* through Jun 2019*: The owner has continued to notice fleas. The dog's excursion history is unknown. The pet owner states that she has bathed the dog monthly with a mixture of baby shampoo and dish soap to help kill the fleas. Unknown date: The dog presented to the veterinary clinic. The dog was diagnosed with anemia, secondary to persistent fleas. It is unknown what other diagnostics were performed. 14 Jun 2019: The dog's current condition is ongoing. There a total of 4 canines and 1 felines in the report, but it is unknown how many animals are in the household.See related cases 19US034915, 19US034918, 19US035690, 19US035694, and 19US035698. No further medical information expected.
14-Jun-2019	UAE; 19US035698; FL; U.S.A	**Species:** Canine **Breed:** Mastiff **Sex:** M **Sex qualifier:** -	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	01-Jun-2019*	14-Jun-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 14 Jun 2019, the pet owner reported to SafetyCall International (SCI) the following event for Deuce, a 4 year old*, 220 pound, intact male Neopolitan Mastiff. Unknown date, years ago: The dog began receiving FRONTLINE

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		Age: 3.00 Year(s) **Weight:** 220 lbs				9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					PLUS FOR DOGS (unsubstantiated) (lot unknown) monthly with unknown purchase history. It is unknown how the product was applied. Mar 2019* through Jun 2019*: The owner has continued to notice fleas. The dog's excursion history is unknown. The pet owner states that she has bathed the dog monthly with a mixture of baby shampoo and dish soap to help kill the fleas. Unknown date: The dog presented to the veterinary clinic. The dog was diagnosed with anemia, secondary to persistent fleas. It is unknown what other diagnostics were performed. 14 Jun 2019: The dog's current condition is ongoing. There a total of 4 canines and 1 felines in the report, but it is unknown how many animals are in the household. See related cases 19US034915, 19US034918, 19US035690, 19US035694, and 19US035695. No further medical information expected.
20-Jun-2019	UAE; 19US035731; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 9.00 Week(s) **Weight:** 2.5 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Capstar; Dawn dish detergent; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Jun-2019	20-Jun-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jun 2019, the pet owner reported the following event for two 9 week old, 2.5 pound, indoor-only felines of further unknown signalment. 28 May 2019*: The reporter acquired both kittens who had an unknown number of fleas on their bodies. Unknown date: Both kittens were treated with Capstar as they were too young to receive any longer lasting parasitic treatment. 17 Jun 2019*: The kittens were bathed in Dawn dish detergent. 18 Jun 2019: Each kitten received one vial of FRONTLINE PLUS CATS (R41118AW) applied topically between the shoulder blades by the pet owner for the first time. An unknown duration following application, the reporter noticed the fleas on the kittens had died. 20 Jun 2019: Both kittens are reinfested with fleas which the reporter feels are not dying. No information regarding the home could be confirmed. No further medical information expected.
20-Jun-2019	UAE; 19US035733; GA; 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:** Dawn; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Feb-2019	20-May-2019	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jun 2019, an owner reported the following event for a 65 pound, unknown canine of further unknown signalment. 20 Feb 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (P61601AR) topically between the shoulder blades. 20 Mar 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS topically between the shoulder blades. 20 Apr 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS topically between the shoulder blades. 20 May 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS topically between the shoulder blades. Owner saw 10-15 fleas on dog. 20 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS topically between the shoulder blades. Owner saw 10-15 fleas on dog. There is one other dog in the house, a 9 pound unknown canine of further unknown signalment (reference case 19US035754). Owner is taking care of everthing dog comes in contact with and is picking 10-15 fleas per day off of dog. Owner baths dog appropriately in regards to time window. Owner uses dawn for bathing the dog. Dog has not been seen by veterinarian and owner has not pursued any treatments for the home or environment. Not seeing any fleas in house. No further medical information expected. UPDATE 27 Jun 2019: Owner waits at least 24 hours after application of product before bathing the dog. The dog is

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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
											indoor/outdoor. The other dog in the home is also being treated with FRONTLINE PLUS. No further medical information expected.
20-Jun-2019	UAE; 19US035742; NY; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 11 - 13 lbs	-	-	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-Jun-2019	16-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jun 2019, the owner reported the following event for 2 felines, 1 male and 1 female, weighing 11-13 pounds, and 9 years of age, all other signalment unknown. 16 Jun 2019: One vial of the FRONTLINE PLUS CATS (S40815) was applied topically in between the shoulder blades by the owner. Fleas were seen prior to treatment. 17 Jun 2019: The owner noticed a small amount of fleas on the cats. The pets are indoor only and have no access to the outside. There are no visiting pets and no wildlife seen in the area Fleas have been seen for 4 days on both cats. The pets have been on FRONTLINE previously at an unknown date. No further medical information is expected. UPDATE 03 Jul 2019: After further review, corrected the local assessment agency.
20-Jun-2019	UAE; 19US035752; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	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?:** Unknown to Company	25-May-2019	20-Jun-2019	26 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jun 2019, the pet owner reported the following event for a canine of unknown signalment. 25 May 2019: One dose of FRONTLINE PLUS DOG (product unsubstantiated) was applied topically between the shoulder blades of the dog by the animal owner. 20 Jun 2019: The owner observed 4-5 live fleas on the dog. There are 2 other dogs in the home who also received FRONTLINE PLUS on 25 May 2019 but who do not seem to be experiencing any issues with fleas. The dogs spend a majority of their time outside on a large wooded lot as well as in a hay field. It is unknown if the dogs are bathed regularly. Per the owner, a portion of the wooded lot has been treated for fleas and ticks. No further medical information expected.
20-Jun-2019	UAE; 19US035754; GA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 9 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	20-Feb-2019	20-May-2019	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jun 2019, an owner reported the following event for a 9 pound, unknown canine of further unknown signalment. 20 Feb 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S61902AL) topically between the shoulder blades. 20 Mar 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS topically between the shoulder blades. 20 Apr 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS topically between the shoulder blades. 20 May 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS topically between the shoulder blades. Owner saw 10-15 fleas on dog. 20 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS topically between the shoulder blades. Owner saw 10-15 fleas on dog. There is one other dog in the house, a 65 pound unknown canine of further unknown signalment (reference case 19US035733). Owner is taking care of everthing dog comes in contact with and is picking 10-15 fleas per day off of dog. Owner baths dog appropriately in regards to time window. The owner uses dawn to bathe the dog. Dog has not been seen by veterinarian and owner has not pursued any treatments for the home or environment. Not seeing any fleas in house. No further medical information

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											expected. UPDATE 27 Jun 2019: The dog is indoor/outdoor. The owner waits at least 24 hours after product administration before bathing the dog. The other dog in home is also being treated with FRONTLINE PLUS. No further medical information expected.
06-Jun-2019	UAE; 19US035818; TN; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 45 - 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	16-May-2017	16-May-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 6 Jun 2019, the pet owner reported the following event for a 45 to 50 pound*, male , Large crossbred. All other signalments unknown. 16 May 2019:It is unknown if the dog was having an issue with fleas. 1 vial of FRONTLINE PLUS DOG 45-88 LBS(S6211AL) was applied to the dog in one area between the shoulder blades. The owner has been seeing a medium amount of fleas on the dog since the application. The dog goes out for potty breaks and recreation in fenced in yard. The dog has no history of skin issues and has not had a bath recently. There is one other dog in the home that was treated with FRONTLINE and has had an issue with fleas since the most recent application 16 May 2019 ,see casae 19US032321. The owner has been treating the dog with FRONTLINE PLUS year round since 2017*.There is one cat in the home treated with FRONTLINE PLUS CATS see case 19US035604. No further medical information is expected.
20-Jun-2019	UAE; 19US035821; -; 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	03-Jun-2019	20-Jun-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jan 2019, a pet owner reported the following event for an unknown Feline of further unknown signalment. 03 Apr 2019, 03 May 2019, and 03 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (lot unknown) topically between the shoulder blades. 20 Jun 2019: Owner saw fleas on the cat. The cat is the only animal in the home, is not bathed by the owner and has no history of skin problems. The cat is an indoor and outdoor cat. Owner had yard and perimeter of the home treated. Owner has not seen fleas in the house. No further medical information expected. UPDATE 03 Jul 2019: After further review, corrected the local assessment agency.
20-Jun-2019	UAE; 19US035840; TX; U.S.A	**Species:** Canine **Breed:** Schnauzer (Miniature) **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 10 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	11-Jun-2018*	19-Jun-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jun 2019, the pet owner reported the following event for Buster, a male neutered, 10 pound, 12 year old, Schnauzer (miniature). 11 Jun 2018*-11 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S60714AX) topically to skin between the shoulder blades of Buster monthly on year round basis. 11 Jun 2019: The pet owner bathed the dog with unknown shampoo. 19 Jun 2019: The pet owner noticed 5-15 fleas on the dog. The pet owner bathed the dog with unknown shampoo. Buster was in good health at time of application. Buster was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has seen fleas in the home. Buster has no history of skin problems or any other issues with topical treatments. Buster has not had flea problem before in the past. Buster has not received any other medications or topical treatments. Buster is indoors and outside. The current status of Buster is unknown. No further medical information.

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20-Jun-2019	UAE; 19US035848; -; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Unknown **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:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Jun-2019	20-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 June 2019, the owner reported the following event for a 7 years old, 80 pounds, female, Pit Bull (all other signalments unknown). 19 June 2019: The first chew of FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown) was applied between the shoulder blades, by the pet owner. 20 June 2019: The dog had fleas. The dog was bathed in a unknown flea shampoo on an unknown date. The owner is not seeing any flea activity in the home. There has been fosters kittens in the home in the past. The dog has access to two large empty lots. No further medical information is expected.
20-Jun-2019	UAE; 19US035856; KS; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 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	03-May-2019	10-May-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jun 2019, the pet owner reported the following event for Snoop a male neutered, 54 pound, 10 year old, Pit Bull/ Boxer crossbreed. 3 May 2019- 3 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (S61101AR) topically to skin between the shoulder blades of Snoop on monthly basis. 10 May 2019*: The pet owner noticed 2 attached alive ticks and 1 unknown attached tick on the dog. Snoop was in good health at time of application. Snoop was not presented to veterinarian. Snoop has no history of skin problems or any other issues with topical treatments. Snoop has not had this problem before in the past. Snoop has not received any other medications or topical treatments. Snoop has not been bathed. Snoop is indoors and outside for walks. The current status of Snoop is unknown. No further medical information.
20-Jun-2019	UAE; 19US035868; -; U.S.A	**Species:** Canine **Breed:** Dachshund **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 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	21-May-2019	15-Jun-2019	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jun 2019, the pet owner reported the following event for Ethan, a 4 year old, 35 pound, neutered male, Wire-haired Dachshund. Unknown dates: The canine began receiving one vial of FRONTLINE PLUS DOG 23-44 LBS (J64453) applied topically onto the skin between the shoulder blades by the pet owner. One vial has since been applied monthly on unknown dates. 21 May 2019: One vial was applied as previously described. 15 Jun 2019: An unknown time after being leash walked on a grassy path on an island that same day, the reporter found 15 ticks on Ethan. The specifies and condition of said ticks could not be confirmed; however, they were all ultimately removed by the pet owner. When the reporter has previously used FRONTLINE PLUS DOG 23-44 on Ethan, she's never found any ticks on him; however, no details of his normal home or external environment could be confirmed for comparison. No further medical information expected.
20-Jun-2019	UAE; 19US035903; NY; U.S.A	**Species:** Canine **Breed:** Collie **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 32 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	16-Jun-2019	17-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 20 Jun 2019 a pet owner reported the following event for Oreo, a 32 pound, 2 year old, intact female Collie. 16 Jun 2019: Owner applied 1 vial FRONTLINE PLUS DOG 23-44 LBS (R61020AL) to the skin between the dogs shoulder blades. 17 Jun 2019: Dog vomited 2 to 3 times, became lethargic, and did not want to eat. 19 Jun 2019: Dog ate a small amount of turkey. 20 Jun 2019: Dog ate a hamburger today, but still seems lethargic. The dog has not presented to the clinic or received any treatments.

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						Was the product used ok?: Yes					Dog normally eats people food and sticks. The dog had been receiving the product since Jan 2018* without issue. No further medical information expected.
20-Jun-2019	UAE; 19US035931; PA; U.S.A	**Species:** Canine **Breed:** Pug **Sex:** F **Sex qualifier:** Neutered **Age:** 16.00 Month(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?:** No (Low dose)	12-Jun-2019	20-Jun-2019*	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jun 2019, the pet owner reported the following event for Bella, a 16 month old (6 Feb 2018), 26 pound, spayed female Pug. 1 Jun 2019*: The pet owner removed the Seresto collar from the dog. 12 Jun 2019: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (S61412AL) monthly with 3 vials purchased OTC on an unknown date. The product is applied directly in the skin between the shoulders. 20 Jun 2019: The owner is noticing a severe amount of fleas. The dog was bathed today with Hartz puppy shampoo. The dog does tend to have dry skin sometimes. The dog does frequent a large yard with trees. The dog has not presented to the veterinary clinic. The dog's current condition is ongoing. There are no other animals in the household. No further medical information expected.
20-Jun-2019	UAE; 19US035942; MO; U.S.A	**Species:** Canine **Breed:** Schnauzer **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 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	17-Jun-2019	20-Jun-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: 20 Jun 2019: An owner reported the following event in Peanut; a 1 year old, 19 pound, neutered, male, Schnauzer. 17 Jun 2019: The owner administered one vial of FRONTLINE PLUS DOGS 0-22 LBS (lot unknown, package unavailable) between the shoulder blades topically. The dog was scratching but no fleas were seen. 20 Jun 2019: The owner saw an unknown amount of fleas. Due to the nature of the caller no further details were provided or available.
21-Jun-2019	UAE; 19US035945; NY; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 20.00 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 product used ok?:** No (Treatment / vaccination program not respected)	11-Jun-2019	13-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 21 Jun 2019, the pet owner reported the following event for Mr.Smushy, a male neutered, 12 pound, 20 year old, Domestic Longhair. 11 Jun 2019 and 12 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S40815AW) topically to skin between the shoulder blades of Mr.Smushy monthly on seasonal basis during summer only. 13 Jun 2019: The pet owner noticed Mr.Smushy with hair falling out at application site and red sores. Mr.Smushy was in good health at time of application. Mr.Smushy was not presented to veterinarian. Mr.Smushy has not had any other products at the same time as the FRONTLINE PLUS CATS application. Mr.Smushy does not have history of drug or vaccine reactions. Mr.Smushy has had FRONTLINE prior to reaction. The status of Mr. Smushy is unknown. No further medical information.
20-Jun-2019	UAE; 19US035957; KY; U.S.A	**Species:** Canine **Breed:** Collie **Sex:** M **Sex qualifier:** Unknown	3	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	14-Jun-2019	20-Jun-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jun 2019, a pet owner reported the following event for two 55-65 pound, male, Collies of further unknown signalment. 14 Apr 2019, 14 May 2019, and 14 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOGS

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		Age: - **Weight:** 55 - 65 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					45-88 LBS (lot unknown) topically between the shoulder blades. 20 Jun 2019*: The owner saw an unknown amount of fleas on dogs. Dogs are being treated with Benadryl and Medicated Shampoo. There is one other dog in the home that is of the same size that is a Labrador Retriever and Poodle Mix that has not had any fleas seen on it. There are two kittens that stay outdoors that have only been treated once (reference case 19US035963). Owner states there has been no change in environment and that dogs are bathed and dry before each new application. Owner has used FRONTLINE PLUS (product unsubstantiated) in the past and has also used Advantix. Dog is indoor/outdoor. No further medical information expected.
20-Jun-2019	UAE; 19US035963; KY; 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	14-Jun-2019	20-Jun-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jun 2019, a pet owner reported the following event for two unknown felines of further unknown signalment. 14 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (lot unknown) topically between the shoulder blades. 20 Jun 2019*: The owner saw an unknown amount of fleas on cats. There are three dogs in the home (reference case 19US035957). The cats stay outside all the time. No further medical information expected.
20-Jun-2019	UAE; 19US035986; PA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 15.00 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-Apr-2019*	20-Jun-2019	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Jun 2019, the owner reported the following event for Tink , 15 year old, 15 pound, neutered male, Domestic Longhair Feline. 27 Apr 2019*: The cat started receiving monthly doses of FRONTLINE PLUS CAT (S40815AW) between the shoulder blades. 27 May 2019: Another vial was applied. 6 Jun 2019: The owner noticed fleas bite on her daughter. 20 Jun 2019: The owner found fleas on the cat for the first time. The flea issue is still ongoing. There are no other pets in the household. No further medical information is expected.
20-Jun-2019	UAE; 19US035993; KY; U.S.A	**Species:** Canine **Breed:** Boston Terrier **Sex:** F **Sex qualifier:** - **Age:** 2.00 Year(s) **Weight:** 16 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Tri-Heart; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Mar-2019	15-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the clinic staff reported the following event for Sadie May , a 2 year old, 16 pound, intact female, Boston Terrier. 14 Mar 2019: The patient began receiving FRONTLINE PLUS DOG 5-22 LBS (S6081RX). 14 Apr 2019: The patient received FRONTLINE PLUS DOG 5-22 LBS. 15 Apr 2019*: Fleas were noticed on the patient and the patient was itching. 14 May 2019: The patient received FRONTLINE PLUS DOG 5-22 LBS. 15 May 2019*: Fleas were noticed on the patient and the patient was itching. 14 Jun 2019: The patient received FRONTLINE PLUS DOG 5-22 LBS. 15 Jun 2019*: Fleas were noticed on the patient and the patient was itching.

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											The owner gives FRONTLINE correctly between the shoulder blades. The animals are not bathed unless it is necessary. The owner states while she does not see fleas in the house she does feel itchy lately. She vacuums and cleans the house on occasion. The animal does go outside, but it is short in length. The yard is fenced in, but owner has noticed wild animals in the area. Overall the owner states she is seeing a moderate amount of fleas daily. The owner stated the patient has been on FRONTLINE since 2017* and has not had any problems with the product. It was also stated the animal is on Tri-Heart monthly as well. The owner has not been to the clinic or sought any other treatments. The patient's current condition is ongoing. There a total of 3 canines in the household. Please see cases 19US036915, 19US036856, and 19US036858. No further medical information expected.
21-Jun-2019	UAE; 19US036013; VA; U.S.A	**Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** X **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 10 - 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	04-Apr-2019	09-May-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 21 Jun 2019, the pet owner reported the following event for 2 cats, Sedah, a female spayed, 10 pounds, 5 years old, Feline mixed/ various breeds, and Lucifer, a male neutered, 5 year old, 12 pound, feline mixed/ various breeds. 4 Apr 2019: The pet owner applied one dose of FRONTLINE PLUS CARS (R41206AW) topically to skin between the shoulder blades of the cats for first time this year. 9 May 2019: The pet owner first noticed 1-5* fleas on the cats. 10 May 2019: The pet owner applied one dose of FRONTLINE PLUS CATS topically to skin between the shoulder blades of the cats on monthly basis. 10 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS CATS topically to skin between the shoulder blades of the cats on monthly basis. The cats were in good health at time of application. The cats were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen fleas in the home. The cats have no history of skin problems or any other issues with topical treatments. The cats have not had flea problem before in the past. The cats have not received any other medications or topical treatments. The cats have not been bathed. The cats are indoors and outside. The current status of the cats are unknown. No further medical information.
21-Jun-2019	UAE; 19US036051; GA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 85.000 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?:** No (Overdose)	14-Jun-2019*	21-Jun-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Jun 2019, the owner reported the following event for 3 canines around 85 pounds *with unknown signalment. Jan 2019: The 3 dogs started monthly on FRONTLINE PLUS DOG 89-132 LBS (S62006AX) topically in between the shoulders. 14 Jun 2019*: The most recent dose was applied to all 3 dogs. 21 Jun 2019: The owner reports seeing a small to moderate amount of fleas on all 3 dogs. Theses dogs are considered indoor dogs that only go out for occasional walks. There were no fleas noticed prior to FRONTLINE administration. No further information at this time.
21-Jun-2019	UAE; 19US036070; -; U.S.A	**Species:** Canine **Breed:** Dachshund **Sex:** U	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	21-May-2019	21-Jun-2019*	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Jun 2019, Animal owner reported the following event for a dachshund. All additional signalment is unknown. 21 May 2019: The pet owner applied the full contents of 1 vial of

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		Sex qualifier: Unknown **Age:** - **Weight:** Unknown				9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					FRONTLINE PLUS DOG 5-22 LBS (Lot unknown) topically between the shoulder blades for the first time. *21 Jun 2019: The pet owner mentioned she has a seen a flea or two. All additional information is unknown. No further information expected.
21-Jun-2019	UAE; 19US036131; PA; U.S.A	**Species:** Canine **Breed:** Blue Heeler **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 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-Jun-2019	21-Jun-2019	1 Day(s)	D-B	Suspected Adverse Event: On the 21 Jun 2019, a pet owner reported the following event for Lady, a 45 pound, 1 year, Blue Heeler. 20 Apr 2019: The dog started on monthly FRONTLINE PLUS DOG 45-88 LBS (S62111AL), with 1 dose applied topically between the shoulder blades. 20 Jun 2019: The most recent dose was applied. 21 Jun 2019: At 11:00 am the dog experienced a grand mal seizure, the dog was recumbent, was paddling, was unaware of her surroundings, was shaking and foaming at the mouth. This lasted for about 2 minutes. The dog then recovered and hid in the bathroom. At 12:00 pm the dog experienced another grand mal seizure with the same symptoms which lasted the same amount of time and then recovered in full. The patient has not seen her veterinarian for this reaction and has not been treated. No further medical information expected. UPDATE 03 Jul 2019: After further review, corrected the local assessment agency.
21-Jun-2019	UAE; 19US036191; FL; U.S.A	**Species:** Canine **Breed:** Terrier (Jack Russell) **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	16-Jun-2019	16-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 21 June 2019, the owner reported the following event for a female, Terrier (Jack Russell) (all other signalments unknown). 15 June 2019: The pet owner bathed the dog in dawn detergent. The owner treated the outside environment and inside the home with an unknown treatment. 16 June 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades, by the pet owner. The pet owner stated that he noticed fleas immediately after application of the product. 20 June 2019: The dog was bathed with dawn and lemons. The owner is not seeing any flea activity in the home. The dog does go outside for bathroom breaks. It is unknown if fleas were seen before application of the product. No further medical information is expected.
21-Jun-2019	UAE; 19US036199; CA; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 13 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	18-Jun-2019	18-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 21 Jun 2019, the pet owner reported the following event for Lucy, a 6 year old, 13 pound*, spayed female, Maltese/Poodle mix. 2017*: The canine began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) applied topically between the shoulder blades and a vial has since been applied monthly on the eighteenth. The most recent dates of application are 18 May 2019 and 18 Jun 2019. Immediately following every single FRONTLINE PLUS application, Lucy was very itchy as if the pet owner 'dumped a bucket of fleas' on her. Likewise, the symptoms always resolved without treatment about 4 to 7 days after onset, though her current status is unknown. On unknown dates prior to product application, Lucy was bathed with unknown shampoo. This unknown shampoo was used at

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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
											every routine grooming and was not a treatment for any of the reported events. There is a litter mate in the home that received the product and experienced the same issue. Please see case 19US036534. No further medical information expected. UPDATE 03 Jul 2019: After further review, corrected the local assessment agency.
21-Jun-2019	UAE; 19US036200; -; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Lactating **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	Jun-2019*	Jun-2019*	0 Day(s)	D-B	Suspected Adverse Event: On 21 Jun 2019 the pet owner reported the following event for an unknown intact female, non pregnant, lactating Yorkshire Terrier. All other signalments are unknown. *7 Jun 2019: The dog had an unknown amount of puppies. *Jun 2019: At some point after the dog had puppies the owner applied 1 vial of FRONTLINE PLUS DOG (product unsubstantiated) (UNKNOWN) to the dog. The application site is unknown and it is unknown if the dog has had the product before. At an unknown amount of time later the dog began having unknown neurological symptoms. The dog presented to the veterinary clinic at an unknown point but remains at the clinic. It is unknown if the dog was treated or if symptoms are ongoing. The line went dead before any additional information could be provided. No further medical information expected.
21-Jun-2019	UAE; 19US036247; CA; U.S.A	**Species:** Canine **Breed:** Whippet **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 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	11-Jun-2019	18-Jun-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Jun 2019, the pet owner reported the following event for Brinby a female spayed, 37 pound, 7 year old, Whippet. 11 Jun 2018*-11 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 23-44 LBS (S60713AX) topically to skin between the shoulder blades of Brinby monthly on year round basis. 18 Jun 2019: The pet owner noticed 5-15 fleas on the body of Brinby. 19 Jun 2019*: The pet owner bathed the dog with Hartz shampoo. Brinby was in good health at time of application. Brinby was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. Brinby has no history of skin problems or any other issues with topical treatments. Brinby has not had flea problem before in the past. Brinby has not received any other medications or topical treatments. Brinby is indoors and outside for walks. The current status of Brinby is unknown. Brinby share home with 2 other cats that are treated with FRONTLINE PLUS CATS with flea issues and case number 19US036273. No further medical information.
21-Jun-2019	UAE; 19US036273; CA; U.S.A	**Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** X **Sex qualifier:** Neutered **Age:** 1.50 Year(s) **Weight:** 10 - 13 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** hartz shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Jun-2019	18-Jun-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Jun 2019, the pet owner reported the following event for 2 cats, Sasha, a female spayed, 6 year old, 10 pound, feline mixed/various breeds, and Pranky, a male neutered, 1.5 year old, 13 pound, feline mixed/ various breeds. 11 Jun 2018*-11 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S40502AX) topically to skin between the shoulder blades of the cats monthly on year round basis. 10 Jun 2019*: The pet owner bathed the cats with Hartz shampoo. 18 Jun 2019: The pet owner noticed 5-15 fleas on the body of the cats. The cats were in good health at time of application. The cats were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. Pranky no history of skin problems or any other issues with

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											topical treatments, but Sasha has hot spots on skin. The cats have not had flea problem before in the past. The cats have not received any other medications or topical treatments. The cats are indoors and outside. The current status of the cats are unknown. The cats share home with 1 other dog that is treated with FRONTLINE PLUS DOG 23-44 LBS(S60713AX) with flea issues and case number 19US036247. No further medical information.
21-Jun-2019	UAE; 19US036287; -; 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	01-May-2019	09-May-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 21 Jun 2019, animal owner reported the following event for Kiki, a 8 year old, 9 pound, spayed female domestic shorthair cat. 01 May 2019: The full contents of 1 vial of FRONTLINE PLUS CATS (S40301AX) was applied topically between the shoulder blades for the first time. The cat did not have fleas. 09 May 2019: The pet owner saw 3 live fleas on the cat. 01 Jun 2019: Another dose was applied topically and the pet owner was still seeing live fleas. 14 Jun 2019: The pet owner gave the cat a bath for fleas with unknown flea shampoo. There are no other animals in the home. The cat is an indoor/ outdoor cat. The pet owner has not seen fleas in the home. The environment has not been treated. No further information expected.
21-Jun-2019	UAE; 19US036294; VA; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various **Sex:** X **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 7.000 - 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	07-Jun-2019*	19-Jun-2019	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 21 Jun 2019, the pet owner reported the following event for 2 dogs, Bailey, a male neutered, 7 pound, 5years old, Mixed breeds/ various breeds, Chloe, a female spayed, 9 year old, 9 pound, Mixed breeds/ various. 7 Jun 2018*-7 Jun 2019*: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S62405AX) topically to skin between the shoulder blades of the dogs on monthly basis. 19 Jun 2019: The pet owner first noticed 15+ fleas on the dogs. The dogs were in good health at time of application. The dogs were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen fleas in the home jumping and biting her. The dogs have no history of skin problems or any other issues with topical treatments. The dogs have not had flea problem before in the past. The dogs have not received any other medications or topical treatments. The dogs are indoors and outside. The current status of the dogs are unknown. No further medical information.
21-Jun-2019	UAE; 19US036307; -; 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	21-May-2019	21-May-2019	0 Day(s)	D-C	Suspected Adverse Event: On 21 Jun 2019, animal owner reported the following event for Kittles, 5 year old, 15 pound, neutered male domestic shorthaired cat. 21 May 2019: 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. Within 2 hours the cat started scratching at the application site. 22 May 2019: Alopecia occurred at the application site. The cat was continuing to scratch and the area developed sores. The pet owner noted the skin looked like it had burns. 23 May 2019: The cat presented to the vet for an exam. The cat received a steroid injection and advised to wash the area. The owner chose not to bath or wash the area. The sores have healed but alopecia is still present. The cat is overall healthy. No further information expected. UPDATE 03 Jul 2019: After further review, corrected the local assessment agency.

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21-Jun-2019	UAE; 19US036337; CA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 17 - 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?:** Yes	06-Mar-2019	15-Mar-2019	N/A	D-D	Suspected Lack of Efficacy: On 21 Jun 2019, the pet owner reported the following event for Max, a 17 pound, neutered male Miniature Poodle and Joey, a 21 pound, neutered male Miniature Poodle. 6 Mar 2019, 6 Apr 2019, 6 May 2019 6 Jun 2019: The owner applied 1 dose of FRONTLINE PLUS DOG 5-22 LBS (S62106AL) to each dog topically between the shoulder blades. 15 Mar 2019*: The owner observed less than 5 live fleas on each dog. The owner has continued to see between 1 and 5 fleas on each dog. The dogs were not bathed after application and spend the majority of their time indoors, although they do go outside for occasional walks. Per the owner, the dogs have received FRONTLINE PLUS year round for multiple years without having issues with fleas. No further medical information expected.
21-Jun-2019	UAE; 19US036342; CA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 9 - 30 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	16-Jun-2019	17-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 21 June 2019, the owner reported the following event for 2 cats between 9-30 pounds (all other signalments unknown). 16 June 2019: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades, by the pet owner. 17 June 2019: The cats were lethargic and not eating. 21 June 2019: The cats are back eating but still lethargic. No further medical information is expected.
21-Jun-2019	UAE; 19US036378; GA; U.S.A	**Species:** Canine **Breed:** Staffordshire Terrier **Sex:** M **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	04-Jun-2019	16-Jun-2019	12 Day(s)	D-D	Suspected Adverse Event: On 21 Jun 2019 the pet owner reported the following event for Willabee a 4 year old, 62 pounds, male neutered, Staffordshire Terrier. 4 Jun 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (R62001AR) to the skin between the shoulder blades for the first time ever. 16 Jun 2019: The dog was scratching a little bit all over. 18 Jun 2019: The dog developed small welts all over the body. 19 Jun 2019: The welts became larger and the owner called the vet and started the dog on NEXGARD (136 mg) and Benadryl. 21 Jun 2019: The dog fully recovered. The dog has a history of flea allergy dermatitis but the owner has not seen any fleas. No further medical information expected.
17-Jun-2019	UAE; 19US036381; VA; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 20 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	01-Jan-2019	04-Jun-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the pet owner reported the following event for a 20 pound*, Shi Tzu. All other signalments unknown. 4 Jun 2019: 1 vial of FRONTLINE PLUS DOG 5-22 LBS(lot and expiration unknown) was applied to the dog in one area between the shoulder blades. The owner has been seeing a small amount of fleas on the dog everyday since the application. The owner bathed the dog in an unknown shampoo to removed the fleas. The owner has been seing fleas on the dog daily since the bath. The owner has been treating monthly with FRONTLINE since Jan. 2019. There is one other dog in the home who was treated with FRONTLINE, see case 19US34658. There are no fleas in the home. The dog has no history of skin issues. The dogs go out for potty breaks and recreation in a yard where fleas are present. The

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											owner has treated the yard. No further medical information is expected.
24-Jun-2019	UAE; 19US036395; MA; U.S.A	**Species:** Feline **Breed:** Burmese **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 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	22-Jun-2019	23-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019 the pet owner reported the following event for Henway a 12 year old, 7 pound, male neutered, Burmese cat. 22 Jun 2019: The cat returned home after being gone for 15 days and was covered in ticks. The owner applied 1 vial of FRONTLINE PLUS CATS (S40404) to the skin between the shoulder blades for the first time. 23 Jun 2019: The owner noticed the ticks were still present, alive and attached. There is 1 dog in the home on a different product. The cat is typically indoor only but cat was missing for 15 days. No further medical information expected.
24-Jun-2019	UAE; 19US036407; -; 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-Feb-2016*	31 Day(s)	D-A	Suspected Adverse Event: On 24 Jun 2019, animal owner inquired about expiration dates and reported the following event for her dog. All signalment is unknown. *Jan 2016: The dog received FRONTLINE PLUS DOG 0-22 LBS (lot unknown). The product is unsubstantiated. *Feb 2016: The dog passed away for unknown reasons. All additional inforamtion is unknown. No further information expected. UPDATE 3 JUL 2019: Upon internal review, corrected Outcomes on Event narrative screen to Death and REaction stopped.
24-Jun-2019	UAE; 19US036431; NC; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** X **Sex qualifier:** Mixed **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	20-Jun-2019	24-Jun-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, animal owner reported the following event for her 5 cats. All signalment is unknown. 20 Jun 2019: 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. The pet owner applied due to seeing flea dirt. 24 Jun 2019: The pet owner stated the cats are covered in fleas. The pet owner could not advise if the fleas have increased or decreased since applying the product. There are no other animals in the home and the cats are indoor cats only. The pet owner has been using a flea comb. No further information expected.
24-Jun-2019	UAE; 19US036432; TN; U.S.A	**Species:** Canine **Breed:** Welsh Corgi (Pembroke) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 40 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	14-Jun-2018*	14-Jun-2018*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, the owner reported the following event for a 6 year old, 40 pound, neutered male Welsh Corgi (Pembroke) (all other signalment unknown). *14 June 2018: The dog was treated with one vial of FRONTLINE PLUS DOG 23-44 LBS (S60308AL) topically between the shouder blades. *Unknown date 2018: The dog started to pick up fleas daily and started to itch and scratch. The dog is treated with FL monthly yearround and is picking up 4-6 fleas a day. There are no fleas in the home. The dog is bathed once every few months with an unknown shampoo. The dog is exposed to outdoor environment daily for potty breaks. No further information available.

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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
24-Jun-2019	UAE; 19US036438; GA; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 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 product used ok?:** Yes	15-Mar-2019	01-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 24 June 2019, the owner reported the following event for Neily, 2 years old, 12 pounds, spayed female, Domestic Medium hair (Crossbred). 15 Mar 2019: The cat started on FRONTLINE PLUS on a monthly basis. May 2019*: The pet owner first noticed fleas on the cat. 2 June 2019: The most recent vial of FRONTLINE PLUS CATS(lot unknown) was applied between the shoulder blades, by the pet owner. 3 June 2019*: The cat had 5-6 fleas. The cat was bathed twice in an unknown flea and tick shampoo. The owner is not seeing any flea activity in the home. The cat is strictly indoor. No further medical information is expected.
24-Jun-2019	UAE; 19US036488; OK; U.S.A	**Species:** Canine **Breed:** Pug **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-Jun-2019*	02-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 June 2019, the owner reported the following event for a Pug (all other signalments unknown). 1 June 2019*: The first vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades, by the pet owner. 2 June 2019*: The dog had fleas. The dog was bathed in an unknown shampoo on an unknown date. The owner is not seeing fleas in the home. The dog has access to a fenced in yard. It is unknown if fleas were seen before application of the product. No further medical information is expected.
24-Jun-2019	UAE; 19US036497; AL; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 13 lbs	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?:** Yes	30-May-2019	24-Jun-2019	25 Day(s)	D-D	Suspected Adverse Event: On 24 Jun 2019 the pet owner reported the following event for Duncan, a 12 Year old (born *1 Jan 2007), 13 pound, neutered male Shi Tzu. 30 May 2019: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (R62514BL), 1 vial topically, between the shoulder blades. 14 Jun 2019: The canine was bathed with an unknown product. 24 Jun 2019: The pet owner stated the canine began exhibiting pruritus at the ears and flank and has not received treatment. The canine has been on FRONTLINE PLUS once monthly since *1 Jan 2009 without issue. No further medical information is expected.
24-Jun-2019	UAE; 19US036502; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **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	08-Jun-2019	09-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019 an animal owner reported the following event in a shorthair feline. All other signalment unknown. 08 Jun 2019: The feline was administered 1 vial of FRONTLINE PLUS CATS (lot S410048W) for the first time of the season for a preexisting flea issue. 09 Jun 2019: The feline licked the FRONTLINE PLUS and was foaming at the mouth. 10 Jun 2019: The feline was recovered. 24 Jun 2019: The animal owner reports still seeing fleas. Reported in case 19US036479. There is 1 other cat in the household, and both cats are indoor cats. The animal owner reported that she treated the house with unknown products. The felines are not bathed. No further

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											information provided nor expected. UPDATE 3 Jul 2019: Per internal review the case is a suspected adverse event not a suspected lack of efficacy as previously recorded. No further information is expected.
24-Jun-2019	UAE; 19US036527; -; 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?:** No (Treatment / vaccination program not respected)	23-May-2019	23-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy: On 24 Jun 2019, a pet owner reported the following event for a canine of unknown signalment. 2015: The dog started using FRONTLINE PLUS (product unsubstantiated)(lot unknown) without issue. 23 May 2019: The owner applied FRONTLINE PLUS. 23 Jun 2019: The owner applied another dose 5 days prior to next regularly scheduled dose due to dog biting herself and seeing something black and moving on the dog. The owner said it did not look like fleas. The owner reports they travel all over the US and thinks it could be due to travel. No further medical information expected.
21-Jun-2019	UAE; 19US036534; CA; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 13 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	18-Jun-2019	18-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 21 Jun 2019, the pet owner reported the following event for Ginger, a 6 year old, 13 pound*, spayed female, Maltese/Poodle mix. 2017*: The canine began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (lot unknown) applied topically between the shoulder blades and a vial has since been applied monthly on the eighteenth. 18 Jun 2019: One vial of FL+ (S60401AX) was applied in the manner previously described. Immediately following product application, Ginger was very itchy as if the pet owner "dumped a bucket of fleas" on her. Presently, it's unknown if her symptoms are ongoing. Previously following every FL+ application, she's experienced this same event which has always resolved without treatment about 4 to 5 days after onset. On unknown dates prior to product application, Ginger was bathed with unknown shampoo. This unknown shampoo was used at every routine grooming and was not a treatment for any of the reported events. There is a litter mate in the home that received the product and experienced the same issue. Please see case 19US036199. No further medical information expected.
24-Jun-2019	UAE; 19US036547; -; U.S.A	**Species:** Canine **Breed:** Terrier Breeds (500 Series) **Sex:** F **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 27 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-Jun-2019*	17-Jun-2019*	1 Week(s)	D-D	Suspected Adverse Event: On 24 Jun 2019, the pet owner reported the following event for Harley, a 14 year old, 27 pound*, spayed female, Terrier mix. Unknown dates: The canine received one vial of FRONTLINE PLUS DOG 23-44 LBS (M32016) applied topically between the shoulder blades on unknown seasonal dates without issues. 10 Jun 2019*: One vial of FRONTLINE PLUS was applied in the same manner and location as previously described. This was the first dose applied in 2019 and the date in which she last received this product cannot be confirmed. 17 Jun 2019*: The reporter noticed Harley became very pruritic. She was observed chewing the base of her tail where she has since developed a hotspot, as well as chewing and scratching her lower abdomen and in between her hind legs. Unknown date: The canine was bathed in an unknown medicated

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											shampoo which the pet owner already had from a prior visit at the veterinary clinic. 23 Jun 2019: The reporter administered an unknown dose of Benadryl which temporarily relieved Harley's discomfort. 24 Jun 2019: Another unknown dose of Benadryl was given and like before, she only experienced temporarily relief before the itching returned. To date, fleas are not being found on the canine, in the home, or getting onto the reporter. Harley has a history of suspected environmental allergies which the reporter suspects is the reason behind Harley's ongoing symptoms. There are no other dogs in the home. No further information.
24-Jun-2019	UAE; 19US036552; SC; U.S.A	**Species:** Canine **Breed:** Lhasa Apso **Sex:** M **Sex qualifier:** - **Age:** 10.00 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	20-Jun-2019	20-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 24 Jun 2019, a pet owner reported the following event for Bentley a 15 pound, 10 year old, intact male, Lhasa Apso. 20 Jan 2007: The dog started on monthly FRONTLINE PLUS 5-22 LBS (S61006AL) with 1 dose applied topically between the shoulder blades year round without any issues. There are no other dogs or animals in the home. Jun 2019: The owner went on a beach vacation and took Bentley with her. While at the beach the pet owner noticed that Bentley would scratch from time to time but did not notice if he had any fleas. When the owner returned home she noticed that the dog was still scratching. 20 Jun 2019: The owner applied the most recent dose to the dog and he noticed that he had fleas. The dog is mostly indoors he only goes outside for potty breaks, but when he goes out for potty breaks, he goes to the same spot which is near a shaded bush. 24 Jun 2019: The pet owner still noticed the dog has about 10-15 fleas on her dog. She is not seeing fleas in her home only on the dog. No further medical information expected.
24-Jun-2019	UAE; 19US036563; -; 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:** KEPPRA; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Jun-2019*	08-Jun-2019*	1 Day(s)	D-C	Suspected Adverse Event: On 24 Jun 2019 an animal owner reported the following event in a canine. All other signalment withheld. 07 Jun 2019*: Canine received FRONTLINE PLUS (product unsubstatiated)(lot, expiration unknown as it was withheld) for the first time. 08 Jun 2019*: The canine was acting unusual. 09 Jun 2019*: The canine had a seizure. The canine has a preexisitng history of seizures since May 2019 and is currently taking Keppra. Due to nature of the call, no further information provided nor expected.
24-Jun-2019	UAE; 19US036565; TX; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 18 - 20 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE	25-Apr-2019*	26-Apr-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, the pet owner reported the following event for 2 dogs, Kimber, a female spayed, 18 pound, 4 years old, Mixed breeds/ various breeds, and Talby, a female spayed, 20 pound, 15 year old, Mixed breed/ various. Unknown dates: The pet owner administers unknown HEARTGARD PLUS (lot unknown, expiration unknown) (Product unsubstantiated) on partial year round basis. 25 Apr 2019*: The pet owner first noticed 15+ fleas on the dogs. The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) topically to skin between the shoulder blades of the dogs on monthly basis.

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						68MCG/163MG; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					26 Apr 2019: The pet owner continued to see 15+ fleas on the dogs. 25 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) topically to skin between the shoulder blades of the dogs on monthly basis. 15 Jun 2019: The dogs were presented to veterinarian and prescribed NEXGARD. The dogs were in good health at time of application. The home environment has been treated by pet owner. The pet owner has not seen fleas in the home jumping and biting her. The dogs have no history of skin problems or any other issues with topical treatments. The dogs have not had flea problem before in the past. The dogs have not received any other topical treatments. The dogs are indoors and outside in fenced yard. The current status of the dogs are unknown. The dogs share home with one other dog that is treated with FRONTLINE PLUS DOG 89-132 (S62904AX) with case number 19US036592. No further medical information.
24-Jun-2019	UAE; 19US036571; WA; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 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	23-Jun-2019	24-Jun-2019	1 Day(s)	D-C	Suspected Adverse Event: On 24 Jun 2019, a pet owner reported the following event for Bitzy, a 5 year old, 60 pound, spayed female Pit Bull. 2016*: The dog began receiving FRONTLINE PLUS DOG 45-88 LBS (S62408AX), topically between the shoulder blades monthly as needed without any adverse events noted. 23 Jun 2019: The most recent application was applied. 24 Jun 2019: This morning when the dog came out of her kennel, she was stumbling and having difficulty walking. The owner had to hold the dog's food bowl up to her mouth so she could eat. There is 1 other dog in the home that is on the same size FRONTLINE and that dog is acting fine. The pet owner did state that Bitzy may have licked the product off of the other dog. No treatments had been provided at the time of the call. No further medical information expected.
24-Jun-2019	UAE; 19US036592; TX; U.S.A	**Species:** Canine **Breed:** Great Dane **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 110 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 272MCG/652MG ; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	25-Apr-2019*	26-Apr-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, the pet owner reported the following event for Kona, a female spayed, 110 pound, 8 years old, Great Dane. Unknown dates: The pet owner administers unknown HEARTGARD PLUS (lot unknown, expiration unknown) (Product unsubstantiated) on partial year round basis. 25 Apr 2019*: The pet owner first noticed 15+ fleas on the dog. The pet owner applied one dose of FRONTLINE PLUS DOG 89-132 LBS (S62904AX) topically to skin between the shoulder blades of the dog on monthly basis. 26 Apr 2019: The pet owner continued to see 15+ fleas on the dog. 25 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 89-132 LBS (S62904AX) topically to skin between the shoulder blades of the dog on monthly basis. 15 Jun 2019: The dog was presented to veterinarian and prescribed NEXGARD. The dog was in good health at time of application. The home environment has been treated by pet owner. The pet owner has not seen fleas in the home jumping and biting her. The dog has no history of skin problems or any other issues with topical treatments. The dog has not had flea problem before in the past. The dog has not received any other topical treatments. The dog is indoors and outside in fenced yard. The current status of the dog is unknown. The dog share home with two other dogs that is treated with FRONTLINE PLUS DOG 5-22 LBS (S61006AL) with case number

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											19US036565. No further medical information.
24-Jun-2019	UAE; 19US036597; CA; U.S.A	**Species:** Canine **Breed:** Terrier Breeds (500 Series) **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Month(s) **Weight:** 12 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?:** No (Treatment / vaccination program not respected)	06-Jun-2019	23-Jun-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, the pet owner reported the following event for Winter, an 8 month old 12 pound male neutered Terrier mix. 6 Jun 2019: The dog was given a dose of FRONTLINE PLUS DOG 5-22 (S61902AL) down to the skin at the neck for the first time. 23 Jun 2019 and 24 Jun 2019: The pet owner found a flea on the dog. The dog has been swimming twice since application. There are no fleas in the home. The dog does go outside in the yard. There is another dog in the home who is also on FRONTLINE but the owner has not found fleas on that dog. No further medical information expected.
24-Jun-2019	UAE; 19US036613; IL; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.50 Year(s) **Weight:** 12.5 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)	22-Jun-2019*	22-Jun-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 24 Jun 2019, a pet owner reported the following event for Herb, a 1.5 year old, 12.5 pound, neutered male Domestic Shorthair. 1 Apr 2019*: The cat received FRONTLINE PLUS FOR CATS (Lot and Expiration Unknown), topically between the shoulder blades in one spot for the treatment of fleas. 15 Jun 2019: The pet owner bathed the cat because he was seeing a moderate amount of fleas on him. After the cat was dry, the owner applied 1 dose of FRONTLINE topically between the shoulder blades in one spot. 22 Jun 2019*: The roommate was getting bit by fleas and applied another dose of FRONTLINE on the cat. 23 Jun 2019*: The pet owner noticed that the back of the cat's neck was red where the FRONTLINE had been applied and found vomit on the floor. The owner lives in an apartment and has been there since Mar 2019. The apartment complex is located next to a field. There are no other pets in the home and the cat is indoor only. No further medical information expected.
24-Jun-2019	UAE; 19US036618; -; 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	24-Jun-2018	24-Jul-2018*	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, the pet owner reported the following event for a canine of unknown signalment. 24 Jun 2018: The owner applied 1 dose of FRONTLINE PLUS (product unsubstantiated) (lot and expiration unknown). Jul 2018*: The owner observed an unknown number of fleas on the dog. Further information regarding the environment, previous FRONTLINE usage, bathing routines and other animals in the home are unknown as the owner declined to make a report. No further medical information expected.
24-Jun-2019	UAE; 19US036633; -; U.S.A	**Species:** Canine **Breed:** Beagle **Sex:** M **Sex qualifier:** - **Age:** 7.00	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	10-Mar-2019	01-Apr-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, animal owner reported the following event for a 7 month old, 17 pound, intact male beagle. 10 Mar 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 0-22 LBS (Lot unknown/ package

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		Month(s) **Weight:** 17 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					unavailable) topically between the shoulder blades for the first time. 01 Apr 2019: The pet owner found engorged ticks on the dog. 10 Apr 2019 - 10 Jun 2019: The pet owner applied the dose. 24 Jun 2019: The pet owner continues to find engorged ticks on the dog every month. The dog is mostly indoors but does play in high grass/ wooded areas. There are no other dogs in the home. The tick species have not been identified. No further information expected.
24-Jun-2019	UAE; 19US036635; VA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 26 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	09-Jun-2019	17-Jun-2019*	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 June 2019, the owner reported the following event for Kuzco, 8 years old, 26 pounds, neutered male, Domestic Shorthair (Crossbred). Nov 2018*: The cat started using the FRONTLINE PLUS on a monthly basis. 9 June 2019: The most recent vial of FRONTLINE PLUS CATS (S40606) was applied between the shoulder blades, by the pet owner. 17 June 2019*: The dog had fleas. The cat does not get bathed. The owner is not seeing any flea activity in the home. The cat is indoor only. No further medical information is expected.
24-Jun-2019	UAE; 19US036640; IN; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 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?:** No (Contraindication per label)	02-Jun-2019*	24-Jun-2019*	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, the pet owner reported the following event for Buffy , a 4 year old*, 15 pound, Shih Tzu/Bichon Frise mix. 1 Apr 2019*: The dog began receiving FRONTLINE PLS DOG 5-22 LBS (S62502) monthly with 3 vials purchased on unknown date from Petsmart. The product is applied down the back, from the base of the neck to the base of the tail. 24 Jun 2019*: The owner is not seeing fleas, but has noticed flea dirt and the dog is scratching. The dog does routine get groomed every 8 weeks. The dog presented to the veterinary clinic on an unknown date. Treatments have been initiated by switching to Bravecto . The dog's current condition is ongoing. There are no other animals in the household. The clinic veterinarian had advised that FRONTLINE is no longer effective . No further medical information expected.
24-Jun-2019	UAE; 19US036679; KS; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** - **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?:** Yes	17-Jun-2019	19-Jun-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, the pet owner reported the following event for Nero, a male intact, 65 pound, 4 year old, Large Crossbreed. 17 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (S62204AX) topically to skin between the shoulder blades of Nero for the first time. 19 Jun 2019: The pet owner noticed 15+ fleas on the body of Nero. 20 Jun 2019: The pet owner bathed dog with unknown shampoo. Nero was in good health at time of application. Nero was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. Nero has no history of skin problems or any other issues with topical treatments. Nero has had flea problem before in the past and it never resolved. Nero has not received any other medications or topical treatments. Nero is indoors and outside for walks. The current status of Nero is unknown. No further medical information.

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21-Jun-2019	UAE; 19US036725; CA; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 127 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	21-Jun-2019	21-Jun-2019	0 Day(s)	D-D	Suspect Adverse Event: On 21 Jun 2019, an owner reported the following event, through Safety Call International (SCI), for Macho, a 12 year old (21 Jun 2007), 127 pound, neutered male, Labrador Retriever. 21 Jun 2019: One vial of FRONTLINE PLUS FOR DOGS 89-132 LBS (S60906AR) was applied topically, site of administration is unknown. Application site is turned brown/black in color two hours after product administration. Dog is showing no signs of discomfort, and no treatments have been performed. Owner stated dog was bathed approximately 5 weeks ago. No further medical information expected. UPDATE 03 Jul 2019: After further review, corrected the local assessment agency.
24-Jun-2019	UAE; 19US036728; GA; 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	01-May-2019*	24-Jun-2019	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019 the pet owner reported the following event for a feline of unknown signalment. 1 May 2019*: The pet owner administered FRONTLINE PLUS CATS (lot number unknown), 1 vial topically, at the base of the neck for the first time. 1 Jun 2019*: The most recent dose was applied. 24 Jun 2019: The pet owner reported seeing approximately 2 fleas on the feline. The feline spends the entirety of their time inside the home. There are two canines in the household that are also on FRONTLINE that are showing no signs of fleas. No further medical information is expected.
24-Jun-2019	UAE; 19US036767; MO; U.S.A	**Species:** Feline **Breed:** Siamese **Sex:** X **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 12.000 - 15 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	25-May-2019	17-Jun-2019*	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, the pet owner reported the following event for 3 cats, Mezzy, a female spayed, 15 pounds, 13 years old, Feline mixed/ various breeds, Scrappy, a male neutered, 1 year old, 12 pound, Feline mixed/ various breeds, and Coco, a female spayed, 1 year old, 12 pounds, Feline mixed/various breeds. Unknown dates: The pet owner has used FRONTLINE PLUS CATS in the past. 25 May 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S40815AW) topically to skin between the shoulder blades of the cats on monthly. 17 Jun 2019*: The pet owner continued to see 1-5 fleas on the cats. The cats were in good health at time of application. The cats were not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen fleas in the home. The cats have no history of skin problems or any other issues with topical treatments. Mezzy has had flea problem before in the past and it resolved. The other cats have not had flea problem before in the past. The cats have not received any other medications or topical treatments. The cats have not been bathed. The cats are indoors only. The current status of the cats are unknown. No further medical information.
24-Jun-2019	UAE; 19US036771; MI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	01-Jun-2019	21-Jun-2019	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, the owner reported the following event for a 45 pound, male canine (all other signalments unknown). 1 Jun 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S60809AX) was applied between the shoulder blades. 21 Jun 2019: The owner noticed the dog itching and fleas.

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		Unknown **Age:** - **Weight:** 45 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					24 Jun 2019: The issue is still ongoing. No fleas were noted in the household. The dog has access to a fenced in yard. The dog has received the product on 1 May 2019 with no prior issue. There is a cat in the household also experiecing an issue (see case 19US039784). No further medical information is expected.
25-Jun-2019	UAE; 19US036774; IN; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **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	01-Jun-2018*	20-Jun-2019*	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the pet owner reported the following event for Kitty, a 1 year old, 10 pound, neutered male Domestic Shorthair. 2018*: The cat began receiving monthly doses of FRONTLINE PLUS FOR CATS (S40502AX) applied topically year-round between the shoulder blades by the owner. 1 April 2019, 1 May 2019, 1 Jun 2019: The most recent doses were applied. 20 Jun 2019*: The owner observed more than 10 fleas in the home and on the cat. Flea populations seem to be increasing. The cat spends his time both indoors and outdoors. There are no other pets in the home and the home has been treated for fleas. The cat does not receive baths. No further medical information expected.
25-Jun-2019	UAE; 19US036782; CT; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 50 - 80 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dog Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Mar-2019	14-Jun-2019*	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019 the pet owner reported the following event for 3 unknown 50 pound, 60 pound and 80 pound Large Crossbred (>20 kg) canines. All other signalments are unknown. *11 Mar 2019: The owner noticed the dogs had some fleas. 11 May 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S62202AX) to the skin between the shoulder blades of each dog for the first time. 11 Jun 2019: The owner applied the most recent dose. *14 Jun 2019: The owner began noticing Medium amounts of fleas. There are no other pets in the home. The dogs are bathed every 2 weeks with a dog shampoo with an unknown start date and unknown end date. The dogs have access to a fenced in back yard to go potty. The owner is not seeing any indoor flea activity present. One of the dogs is also having ticks with case 19US036802. No more medical information expected.
25-Jun-2019	UAE; 19US036788; PA; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** - **Age:** 10.00 Year(s) **Weight:** 8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** PO-Oral **Was the product used ok?:** Yes	25-May-2019	10-Jun-2019*	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the animal owner reported the following event for Squirrel, a 10 year old, 8 pound, intact male, Chihuahua. 25 May 2019: He received his monthly dose of FRONTLINE PLUS DOG 5-22 LBS (S61902AL). This was applied correctly by the owner and Squirrel has been on FRONTLINE monthly since 25 Feb 2019. 10 Jun 2019*: The owner started to noticed fleas on the animal, and that the animal had been itching due to this. There were no other products given at the same time to the animal, and the owner stated the animal is only bathed when needed. The owner stated she is not seeing fleas on herself or in the house. She has been vacuuming daily to help prevent fleas. Her yard is in a wooded area and the dog goes out about four times daily to go potty. The owner stated she is seeing about 10 fleas daily. The animal has no prior reactions to any other drugs, and is currently not gotten any further treatments for the fleas. The animal's current condition is ongoing.

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											There a total of 1 canine and 1 feline in the household. Please see case 19US037818 for the feline's event. No further medical information expected.
25-Jun-2019	UAE; 19US036800; 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	08-Jun-2019	24-Jun-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019 an animal owner reported the following event in 2 canines. No further signalment provided. 08 Jun 2019: The 2 canines were each administered 1 entire vial of FRONTLINE PLUS DOGS 45-88 LB (lot S62202AX) between the shoulder blades. No fleas seen at time of application. 24 Jun 2019: The animal owner reported seeing 10-12 fleas on each canine. The canines were bathed in an unspecified shampoo. There are no other pets in the home. The canines have outdoor access, but no outdoor animal exposure. No further information provided nor expected.
25-Jun-2019	UAE; 19US036802; CT; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 80 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dog Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-May-2019	04-Jun-2019*	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019 the pet owner reported the following event for an unknown 80 pound Large Crossbred (>20 kg) canines. All other signalments are unknown. 11 May 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S62202AX) to the skin between the shoulder blades for the first time. *4 Jun 2019: The owner noticed 2 ticks on the dog that were attached and alive. It is unknown if they were engorged. There are 2 other pets in the home with no issue with ticks but issues with fleas with case 19US036782. The dog is bathed every 2 weeks with a dog shampoo with an unknown start date and unknown end date. The dog has access to a fenced in back yard to go potty. No more medical information expected.
25-Jun-2019	UAE; 19US036826; -; 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	21-Jun-2019	21-Jun-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 25 Jun 2019, the owner reported the following event for an unknown feline (all signalments unknown). 21 Jun 2019: The owner applied 1 vial of FRONTLINE PLUS CATS (lot unknown) topically between the shoulder blades. The cat was able to reach around and lick the product. An unknown amount of time later, the cat started vomiting. The symptoms are ongoing. The owner has used the product before for an unknown amount of time and has had the same problems before when the cat licked the product. The owner declined the complete the report. No further medical information expected.
25-Jun-2019	UAE; 19US036828; NY; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 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**	22-Jun-2019	25-Jun-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: 25 Jun 2019: An owner reporting the following event in Maggie May; a 10 year old, 22 pound, spayed, female, unknown breed. 22 Jun 2019: Reporter stated visible fleas noted and the dog was scratching. The owner applied FRONTLINE PLUS DOGS 5-22 LBS (lot unknown, package unavailable) in an unknown manner. 25 Jun 2019: The owner saw 2-3 live fleas. There are two other dogs in the home (cases 19US036840 and 19US036841) and 2 outdoor cats that are not treated with anything. No further medical information expected. The owner previously inquired (19US018552) about splitting doses from a larger size tube.

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						product used ok?: Unknown to Company					
25-Jun-2019	UAE; 19US036841; NY; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 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?:** Unknown to Company	25-May-2019*	25-Jun-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: 25 Jun 2019: An owner reporting the following event in Mikey; a 2 year old, 65 pound, neutered, male, unknown breed that is mainly outdoors. 25 May 2019*: The owner applied FRONTLINE PLUS DOGS 45-88 LBS (lot unknown, package unavailable) in an unknown manner. It is unknown if fleas were seen at the time of application. 25 Jun 2019: The owner saw 2-3 live fleas on another dog. There are two other dogs in the home (cases 19US036840 and 19US036828) and 2 outdoor cats that are not treated with anything. No further medical information expected. The owner previously inquired (19US018552) about splitting doses from a larger size tube.
25-Jun-2019	UAE; 19US036844; -; U.S.A	**Species:** Canine **Breed:** Great Dane **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 113 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-Jun-2019*	11-Jun-2019*	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the pet owner reported the following event for Iris, a 7 year old*, 113 pound, spayed female Great Dane. 1 Apr 2019*: The dog began receiving FRONTLINE PLUS DOG 89-132 (R61814) monthly with unknown purchase history from Walmart. The product is applied directly on the skin between the shoulders. 1 May 2019*: The monthly dose was applied. No issues with fleas at the time. 1 Jun 2019*: The dog was bathed with Arm & Hammer super deoderizing pet shampoo. The monthly dose was applied shortly after. No issues with fleas at the time. 11 Jun 2019*: The owner noticed a mild case fleas and the dog began scratching. The dog does have access to a fenced yard that borders with a wooded area. The dog also goes on frequent walks to the waterfront. 12 Jun 2019*: Another dose was applied. 15 Jun 2019*: The dog was bathed with Natural Care flea and tick shampoo. The dog has not presented to the veterinary clinic. 25 Jun 2019: The dog's current condition is ongoing. There are no other animals in the household. The pet owner did mention there are outside cats present in the neighborhood, and it is unknown if any neighbor applies fleas prevention to them. No further medical information expected. UPDATE 09 July 2019: Corrected product start date on product screen. No additional case updates.
25-Jun-2019	UAE; 19US036850; -; U.S.A	**Species:** Canine **Breed:** Havanese **Sex:** F **Sex qualifier:** Neutered **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**	24-Jun-2019	25-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 25 Jun 2019 an animal owner reported the following event in a 12 pound, female spayed, Havanese. No further signalment provided. 24 Jun 2019: The canine was administered FRONTLINE PLUS (product unsubstantiated) (lot, expiration unknown as caller withheld) between the shoulder blades for the first time. No fleas were seen at time of administration. 25 Jun 2019: The canine began coughing, scratching at application site, and twitching. Due to nature of call no further information provided nor expected.

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						ok?: Unknown to Company					
20-Jun-2019	UAE; 19US036856; KY; U.S.A	**Species:** Canine **Breed:** Boston Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 16 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Tri-Heart; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Mar-2019	15-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the clinic staff reported the following event for Stella Joe, a 8 year old, 16 pound, spayed female, Boston Terrier. 14 Mar 2019: The patient began receiving FRONTLINE PLUS DOG 5-22 LBS (S6081RX). 14 Apr 2019: The patient received FRONTLINE PLUS DOG 5-22 LBS. 15 Apr 2019*: Fleas were noticed on the patient and the patient was itching. 14 May 2019: The patient received FRONTLINE PLUS DOG 5-22 LBS. 15 May 2019*: Fleas were noticed on the patient and the patient was itching. 14 Jun 2019: The patient received FRONTLINE PLUS DOG 5-22 LBS. 15 Jun 2019*: Fleas were noticed on the patient and the patient was itching. The owner gives FRONTLINE correctly between the shoulder blades. The animals are not bathed unless it is necessary. The owner states while she does not see fleas in the house she does feel itchy lately. She vacuums and cleans the house on occasion. The animal does go outside, but it is short in length. The yard is fenced in, but owner has noticed wild animals in the area. Overall the owner states she is seeing a moderate amount of fleas daily. The owner stated the patient has been on FRONTLINE since 2011* and has not had any problems with the product. It was also stated the animal is on Tri-Heart monthly as well. The owner has not been to the clinic or sought any other treatments. The patient's current condition is ongoing. There a total of 3 canines in the household. Please see cases 19US035993, 19US036915, and 19US036858. No further medical information expected.
20-Jun-2019	UAE; 19US036858; KY; U.S.A	**Species:** Canine **Breed:** Boston Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 36 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Tri-Heart; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Mar-2019	15-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the clinic staff reported the following event for Kenny, a 8 year old, 36 pound, spayed male, Boston Terrier. 14 Mar 2019: The patient began receiving FRONTLINE PLUS DOG 23-44 LBS (S61602RX). 14 Apr 2019: The patient received FRONTLINE PLUS DOG 23-44 LBS. 15 Apr 2019*: Fleas were noticed on the patient and the patient was itching. 14 May 2019: The patient received FRONTLINE PLUS DOG 23-44 LBS. 15 May 2019*: Fleas were noticed on the patient and the patient was itching. 14 Jun 2019: The patient received FRONTLINE PLUS DOG 23-44 LBS. 15 Jun 2019*: Fleas were noticed on the patient and the patient was itching. The owner gives FRONTLINE correctly between the shoulder blades. The animals are not bathed unless it is necessary. The owner states while she does not see fleas in the house she does feel itchy lately. She vacuums and cleans the house on occasion. The animal does go outside, but it is short in length. The yard is fenced in, but owner has noticed wild animals in the area. Overall

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											the owner states she is seeing a moderate amount of fleas daily. The owner stated the patient has been on FRONTLINE since 2011* and has not had any problems with the product. It was also stated the animal is on Tri-Heart monthly as well. The owner has not been to the clinic or sought any other treatments. The patient's current condition is ongoing. There a total of 3 canines in the household. Please see cases 19US035993, 19US036856, and 19US036915. No further medical information expected.
25-Jun-2019	UAE; 19US036867; NC; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** - **Weight:** 70 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn dish soap; Flea shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	03-May-2019	08-May-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019 the pet owner reported the following event for an unknown 70 pound, spayed female Retriever (Golden). All other signalments are unknown 3 Mar 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (UNKNOWN) to the skin between the shoulder blades for the first time and repeated it on a monthly basis thereafter. 3 May 2019: The owner applied another dose and went on vacation. 8 May 2019: The owner returned home and discovered a large amount of indoor flea activity and fleas on the dog. The owner gave the dog a bath in dawn dish soap and repeated baths weekly with a flea shampoo. 19 May 2019: The owner applied another dose. 20 May 2019: The owner continued to see fleas in the home and on the dog. 19 Jun 2019: The owner applied the most recent dose. 20 Jun 2019: The owner continued to see fleas in the home and on the dog. There are 2 outdoor only cats in the home currently using FRONTLINE PLUS with case number 19US036970. The dog is walked through the yard and neighborhood. The owner is seeing large amounts of indoor flea activity. The owner treated the house with Precore and Suspend bombs. The owner also treated the yard with an unknown product on an unknown date. The owner applied a Saresto collar to the dog on an unknown date. The dog has dry skin. No more medical information expected.
25-Jun-2019	UAE; 19US036877; PA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 7 - 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	20-Jun-2019	22-Jun-2019	2 Day(s)	D-D	Suspected Adverse Event: On 25 Jun 2019, the pet owner reported the following event for Mia, a 7 to 8 pound*, 4 year old, female spayed, Domestic Shorthair. 20 Jun 2019: 1 vial of FRONTLINE PLUS CATS (F41108AW) was applied to the cat in one area between the shoulder blades for the very firs time. 22 Jun 2019: Her hair fell out at the application site. The cat has not been seen by the veterinarian. No further medical information is expected.
20-Jun-2019	UAE; 19US036915; KY; U.S.A	**Species:** Canine **Breed:** Boston Terrier **Sex:** U **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:** no other products	01-Mar-2019*	02-Mar-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the clinic staff reported the following event for a 8 year old, Boston Terrier French Bulldog Mix of further unknown signalment. 1 Mar 2019: The patient began receiving FRONTLINE PLUS DOG (Unsubstantiated)(lot unknown). 2 Mar 2019*: Fleas were noticed on the patient at the vet and the patient was itching. 1 Apr 2019*: The animal was switched to a new unknown product

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						Route: Topical / Cutaneous **Was the product used ok?:** Unknown to Company					and has not had fleas issues since. The owner gives FRONTLINE correctly between the shoulder blades. Further information is unknown as the reporter was not the owner of the animal. The reporter also reported a case for 3 other dogs at thit time. Please see cases 19US035993, 19US036856, and 19US036858. No further medical information expected.
25-Jun-2019	UAE; 19US036930; -; U.S.A	**Species:** Canine **Breed:** Maltese **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	01-Jun-2019	25-Jun-2019	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the pet owner reported the following event for Sophie, a female Maltese of unknown signalment. 1 Jun 2019: The dog received her monthly dose of FRONTLINE PLUS DOG 23-44 LBS (lot and expiration unknown) 24 Jun 2019: The dog went to a dog park. An unknown amount of hours afterwards, the owners noted an unknown number of live fleas on the dog. Per the owners the dog has received monthly doses of FRONTLINE PLUS for an unknown number of years. Further details unavailable as the caller declined to make a report. No further medical information expected.
25-Jun-2019	UAE; 19US036933; OR; U.S.A	**Species:** Canine **Breed:** Pomeranian **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 5 lbs*	1	1	1	**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-Jun-2019*	10-Jun-2019*	1 Day(s)	D-A	Suspected Adverse Event: On 25 Jun 2019 a pet owner's mother reported the following event for Tiny, 5 pound*, 11 year old, female spayed Pomeranian. 9 Jun 2019*: Owner applied FRONTLINE PLUS DOG 5-22 LBS (S61017) to the skin between Tiny's shoulder blades for the first time. 10 Jun 2019*: Dog became slightly lethargic. 11 Jun 2019*: Pet owner washed the dog in Dawn dish soap. 13 Jun 2019*: Dog got a drink, laid down by her water bowl, and died. The dog had no known health problems and did not receive continuous medications including heartworm preventative. The owner also reported the second dog in the home died after receiving the product: 19US036945. No further information at this time. UPDATE 26 June 2019: Veterinarian reports dogs have not been to his clinic for medical care since Nov 2016. One of the bodies the owner brought in had maggots and bodies were in a state of decomposition preventing any hopes of a necropsy.
25-Jun-2019	UAE; 19US036945; OR; U.S.A	**Species:** Canine **Breed:** Pomeranian **Sex:** M **Sex qualifier:** - **Age:** 10.00 Year(s) **Weight:** 5 lbs*	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn dish soap; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	16-Jun-2019*	17-Jun-2019*	2 Day(s)	D-A	Suspected Adverse Event: On 25 Jun 2019 a pet owner's mother reported the following event for Bear, a 5 pound*, 10 year old, intact male Pomeranian/Wolf hybrid. 16 Jun 2019*: Owner applied FRONTLINE PLUS DOG 5-22 LBS (S61017) to the skin between Bear's shoulder blades for the first time. 17 Jun 2019*: Pet owner washed the dog in Dawn dish soap. Owner reported during bath something brown came off the dog which she does not believe is dissolved flea feces because she has seen that before. 18 Jun 2019*: Dog started coughing. 20 Jun 2019*: Dog was laying on his bed and was dead. The dog had no known health problems and did not receive continuous medications including heartworm preventative. The dog's body has been on the garage floor since he died. No further information at this time.

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25-Jun-2019	UAE; 19US036983; PA; U.S.A	**Species:** Canine **Breed:** German Shepherd **Sex:** M **Sex qualifier:** - **Age:** 15.00 Month(s) **Weight:** 77.4 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?:** No (Indication not indicated / recommended)	01-Jun-2019*	24-Jun-2019	23 Day(s)	D-C	Suspected Lack of Efficacy Claim: On 25 Jun 2019, a veterinarian reported the following event for Axell, a 15 month old (born 28 Mar 2018), 77.4 pound, intact male German Shepherd. He received a RECOMBITEK LYME, 1 ml, SC, in the right hip on 22 Jun 2018 (42224, 19 Dec 2019), in the left hip on 13 Jul 2018 (42226, 27 Mar 2020), and in the right shoulder on 24 Jun 2019 (42239, 24 Jan 2020). 24 Jun 2019: The dog was diagnosed Lyme antigen positive via a routine Snap 4 DX. The dog is asymptomatic and was started on doxycycline. A Quant C6 has not been performed. His current condition is ongoing. There is no negative Lyme testing history for this dog due to his age. The dog has been receiving FRONTLINE PLUS DOG 45-88 LBS (Unsubstantiated) (Lot and Expiration Unknown) for an unknown amount of time. No further medical information expected.
25-Jun-2019	UAE; 19US037003; FL; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 13 - 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	01-Jun-2019	20-Jun-2019*	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the pet owner reported the following event for a 11 year old, 13-14 pound*, male neutered, Shih Tzu. 1 Jun 2019: The dog was not having an issue with fleas. 1 vial of FRONTLINE PLUS DOG 5-22 LBS(S60401AX) was applied to the dog in one area between the shoulder blades for the very first time. 20 Jun 2019* The owner began to see 1-5 fleas on the dog daily. The dog goes out for potty breaks and recreation on a concrete patio. There are stray cats in the neighborhood. There are no fleas in the home. The dog has not had bath and has no skin issues. There are 2 other dogs in the home who were treated with FRONTLINE, signalments unknown. No further medical information is expected.
25-Jun-2019	UAE; 19US037012; NC; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.50 Year(s) **Weight:** 5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Palmolive; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	17-Jun-2019	23-Jun-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the pet owner reported the following event for Minou, a 5 pound, 3.5 year old, female spayed, Small crossbred. 17 Jun 2019: The dog was not having an issue with fleas. 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S61017)(lot invalid) was applied in one area between the shoulder blades. After the application the owner used a tissue to wipe the product. The owner is seeing 3-5 fleas on the dog daily. 21 Jun 2019: The owner bathed the dog in Palmolive, fresh lemon juice, and water to remove 3-5 fleas. 23 Jun 2019: The owner bathed the dog in Palmolive, fresh lemon juice, and water to remove 3-5 fleas. The owner treats seasonally. The dog has no history of skin issues. The dog uses puppy pads inside. The owner is visiting relative in North Carolina, and there are fleas in the home. No further medical information is expected.
25-Jun-2019	UAE; 19US037073; OH; U.S.A	**Species:** Canine **Breed:** Boston Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 16.5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown manufacturer's	15-Jun-2019	15-Jun-2019*	0 Day(s)	D-C	Suspected Adverse Event: On 25 Jun 2019, the pet owner reported the following event for Bailey, a 5 year old, 16.5 pound, neutered male, Boston Terrier. Unknown dates: As a puppy, the canine began receiving one chew of HEARTGARD PLUS (68 MCG/57 MG) (HG+) (lot and expiration unknown), PO, and one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (lot unknown) applied topically between the shoulder blades. One chew of HG+ has since been given monthly on unknown dates without any issues and one vial of FL+ has since been

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						DHPP vaccine; IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG; Pepcid 5 mg; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					applied as previously described seasonally on unknown dates; specifically, FL+ is applied every three months during the winter and every two months during the summer and the reporter would not specify the months and/or durations for the respective seasons. On an unknown date, Bailey began receiving 5 mg of Pepcid PO BID due to a history of emesis and undefined gastrointestinal (GI) upset. The reporter could not confirm his age at the time of starting on the medication but claimed he's received Pepcid 'since forever'. Moreover, he's continued to receive the same dose and frequency of Pepcid and has done well on it. 24 May 2019: Bailey was vaccinated by an unknown individual with an unknown manufacturer's DHPP vaccine. 1 Jun 2019: The canine received one chew of HG+ (8BC0321, Mar 2021), PO. On the same date, he began boarding at an unknown facility for about three days. Unknown date: He became polydipsic; however, the reporter did not state or imply that she suspected this symptom to be caused by or in any way related to having previously received FL+, HG+, Pepcid, and/or said vaccine. It's also possible that the date of polydipsia onset precedes the most recent administration of HG+, but the reporter provided no clarification. 15 Jun 2019: An unknown time after receiving Pepcid, Bailey received one vial of FL+ (P61304) in the manner previously described. An unknown duration following FL+ application, he received his evening dose of Pepcid. An unknown
25-Jun-2019	UAE; 19US037075; -; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** - **Age:** 8.00 Month(s) **Weight:** 6.44 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	22-Jun-2019	24-Jun-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the pharmacist reported the following event for Charlie, an 8 month old, 6.4 pound, intact male Yorkshire Terrier. 23 Mar 2019, 23 Apr 2019, 24 May 2019, 22 Jun 2019: Single doses of FRONTLINE PLUS DOGS 5-22 LBS were purchased from Vetsource and applied to the dog by the animal owner. 24 Jun 2019*: The owner observed an unknown number of fleas on the dog. There is one other dog in the home, Jerry, who also receives FRONTLINE PLUS with the same purchase dates. Additional details about the dog's environment and FRONTLINE PLUS use is unknown at this time as it was not provided to the reported. No further medical information expected.
25-Jun-2019	UAE; 19US037083; MO; U.S.A	**Species:** Feline **Breed:** Feline mixed/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:** Adam's Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Jun-2019	25-Jun-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the pet owner reported the following event for a Domestic Long Hair cat and a Domestic Short Hair cat of further unknown signalments. 15 Apr 2019*: Owner purchased a 3 pack of FRONTLINE PLUS CATS (lot unknown). 15 May 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (lot unknown) topically between the shoulder blades for the first time to each cat. 01 Jun 2019*: Owner purchased a 3 pack of FRONTLINE PLUS CATS (S40815BW). 08 Jun 2019*: Owner gave the cats baths with Adam's shampoo. 15 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (S40815BW) topically between the shoulder blades of each cat. 25 Jun 2019: Owner is seeing fleas on both cats. The cats are indoor only. There is also a dog of unknown signalment in the house. However, the dog is treated year round and owner isn't seeing any fleas on it. Owner has not noticed a

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											change in the environment and is washing the cat's bedding. Owner is not seeing fleas on them or in the home. No further medical information expected.
25-Jun-2019	UAE; 19US037085; PA; U.S.A	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 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 product used ok?:** Yes	04-Jun-2019	05-Jun-2019	1 Day(s)	D-C	Suspected Adverse Event: On 25 Jun 2019 the pet owner reported the following event for Lucky a 10 year old 30 pound male neutered Poodle (Miniature) mix. *2010: The owner began applying 1 vial of FRONTLINE PLUS DOG 23-44 LBS (UNKNOWN) to the skin between the shoulder blades on a monthly and year round basis. *30 Mar 2019: The owner applied 1 vial from a new lot (UNKNOWN). *31 Mar 2019: The dog seemed sensitive at the application site but no redness or irritation was present. *3 Apr 2019: The dog was fully recovered. *30 Apr 2019: The owner applied another dose with no issue. 4 Jun 2019: The owner applied the most recent dose. 5 Jun 2019: The application site seemed more sensitive. 6 Jun 2019: The application site was red and irritated. The dog would not let the owner clean it with a cloth and dog shampoo despite multiple attempts. 7 Jun 2019: The hair began falling out and application site appeared to have a chemical burn. The owner sprayed a calming aid on the wound and it seemed to help. *12 Jun 2019: The chemical burn and irritation was gone but there were scabs along the dog's application site. The dog has not fully recovered but is doing better. The dog did not present to the vet clinic. No further medical information expected.
25-Jun-2019	UAE; 19US037111; -; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **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:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	25-Jun-2019	25-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: 25 Jun 2019: An owner reported the following event in Monkey; a 5 years old, 6 pounds*, neutered, male, Domestic Long Hair feline. 25 Jun 2019: The owner administered 1 tube FRONTLINE PLUS CATS (lot unknown, package unavailable) topically at the base of the neck for the first time. The cat licked the application site and drooled briefly. The cat fully recovered. No further medical information expected.
25-Jun-2019	UAE; 19US037112; -; 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**	11-Jun-2019	25-Jun-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, a pet owner reported the following event for 3 dogs weighing 5, 6, and 14 pounds. Further signalment is unknown. 11 May 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) topically between the shoulder blades for the first time that year to all the dogs. 11 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) topically between the shoulder blades for all of the dogs. 25 Jun 2019: Owner is seeing fleas on all of the dogs. The dogs only go outside to use the bathroom. No further medical

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						ok?: Yes					information expected as the owner disconnected the call. UPDATE 08 Jul 2019: Owner did not see fleas prior to FRONTLINE administration. No further medical information expected.
25-Jun-2019	UAE; 19US037132; CA; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 15 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	19-Jun-2019*	25-Jun-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the pet owner reported the following event for Sugar, a 6 year old, 15 pound*, intact female, Yorkshire Terrier. Unknown date: Sugar began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (lot unknown) applied topically between the shoulder blades. It is unknown how old Sugar was at the time of first application. One vial of FL+ has since been applied in the same fashion, monthly, on unknown dates, with last application having been given on an unknown date in Apr 2019 (when she ran out of product). May 2019 (unknown date): The reporter began finding an unknown quantity of fleas on Sugar. FL+ was not applied for this month due to inadequate funds to purchase more product. Throughout the month, the pet owner washed all of the dog's bedding and treated her yard with an unknown flea/tick insecticide. Despite actions taken, the pet owner continued to find an unknown amount of fleas on Sugar. 18 Jun 2019*: The pet owner bathed Sugar with an unknown shampoo to get rid of the fleas on her. On approximately the same date, 3 doses of FRONTLINE PLUS DOG 5-22 LBS (S61017AL) were purchased from a local retailer (Walmart). 19 Jun 2019*: Twenty-four hours after being bathed, the reporter applied one vial of FL+ in the fashion previously described. 25 Jun 2019*: The reporter continues to find an unknown number of fleas on Sugar who is also scratching as a result of the fleas. The pet owner continues to not find fleas in the home. There are two other dogs in the home that received FL+ and experienced similar events. Please see cases 19US037389 and 19US037395. The reporter was a bit challenging to get information from therefore information regarding the external environment could not be obtained. No further medical information expected.
25-Jun-2019	UAE; 19US037135; VA; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 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?:** No (Overdose)	04-Jun-2019*	18-Jun-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the pet owner reported the following event for Riley a male neutered, 90 pound, 12 year old, Large Crossbred. 4 Jun 2019*: The pet owner applied one dose of FRONTLINE PLUS DOG 89-132 LBS topically to skin between the shoulder blades of Riley monthly for first this year. 18 Jun 2019*: The pet owner first noticed 5-15 fleas on the dog. The pet owner applied one dose of FRONTLINE PLUS DOG 89-132 LBS (S62904RX) topically to skin between the shoulder blades of Riley monthly. Riley was in good health at time of application. Riley was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen any fleas in the home. Riley has no history of skin problems or any other issues with topical treatments. Riley has not had flea problem before in the past. Riley has not received any other medications or topical treatments. Riley has not been bathed. Riley is indoors and outdoors in fenced yard. The current status of Riley is unknown. No further medical information.
25-Jun-2019	UAE; 19US037145;	**Species:** Canine **Breed:**	1	1	0	**Product used:** FIPRONIL	18-Jun-2019	19-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 25 Jun 2019, the owner reported the following event for Mini, a 7year old, 18 pound, female,

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	KS; U.S.A	Dachshund **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 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					neutered, Dachshund. 18 Jun 2019: One vial of FRONTLINE PLUS DOG (S61009AL) was applied topically in between the pet's shoulder blades by the owner. 19 Jun 2019: The owner noticed hair loss at the application. The owner has not presented the pet to the clinic. 25 Jun 2019: The pet's symptoms are still ongoing. No further medical information expected.
25-Jun-2019	UAE; 19US037146; MD; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** - **Age:** 15.00 Week(s) **Weight:** 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	25-Jun-2019	25-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 25 Jun 2019, the owner reported the following event for Django, 15 week old, 5 pound, Intact male, Maltese canine. 25 Jun 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) was applied between the shoulder blades for the very first time. After an hour the dog experienced vomiting and lethargy. The pet did not present to the clinic and no treatment was provided. Symptoms are still ongoing. No further medical information is expected.
25-Jun-2019	UAE; 19US037147; MO; 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	01-Jun-2014*	25-Jun-2019*	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the pet owner reported the following event for 3 cats, other signalment unknown. Unknown Dates: The cats were treated with FRONTLINE PLUS CATS (lot number unknown) on unknown dates for about 5 years. The three cats presented with fleas on an unknown date. The cats are strictly indoors and the pet owner is currently noticing flea activity in the home. There are 2 dogs in the home treated with FRONTLINE PLUS and are not currently having an issue with fleas. This is the extent of the information available since the pet owner declined to provide pertinent details for the report. No further medical information expected.
26-Jun-2019	UAE; 19US037161; SC; U.S.A	**Species:** Canine **Breed:** Griffon (Brussels) **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 27 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-May-2019	11-May-2019	N/A	D-D	Suspected Lack of Efficacy Claim:26 Jun 2019: An owner reported the following event in ZZ Top; an 8 year old, 27 pound, male, Brussels Griffon, indoor-outdoor dog. 18 May 2019: The owner administered one dose of FRONTLINE PLUS DOGS 23-44 LBS (S60801AL) (purchased from Amazon) topically between the shoulders. There were no fleas seen at the time of application. 11 Jun 2019: The owner saw 1 flea. 18 Jun 2019: The owner administered one dose topically between the shoulders. 04 Jul 2019: The owner saw a few live and dead fleas when bathing in an unknown shampoo. There are no other animals in the home. No further medical information available.
26-Jun-2019	UAE; 19US037167; AL; U.S.A	**Species:** Canine **Breed:** Papillon **Sex:** M **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	23-Jan-2019	09-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On the 25 Jun 2019, a pet owner reported the following event for Bosco, a 12 pound, 9 year old, neutered male, Papillon. 23 Jan 2019: The dog started on monthly FRONTLINE PLUS 5-22 LBS (S6107AL), with 1 dose applied topically between the

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		Age: 9.00 Year(s) **Weight:** 12 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					shoulder blades. The owner was already seeing fleas on the dog but not inside of the home. The owner applies flea and tick products to her dogs year round but switched to FRONTLINE PLUS in January 2019. The dog is inside/outside, however he spends the majority of the time inside of the home. The dog has access to the backyard when he goes outside for his potty breaks. The backyard is fenced in, has grass, bushes and there is a small wooded area that the dog frequents on his potty breaks. The dog has a moderate amount of fleas on him. There are 2 other dogs in the home with the same issue see cases 19US037170 and 19US037172. 23 May 2019: The pet owner missed the monthly dose. 9 Jun 2019: The dog began scratching his abdomen constantly. The pet owner picked him up and noticed that he had small red dots all over his abdomen and he had erythema on the abdomen. 23 Jun 2019: The most recent dose was applied. When she applied the product she noticed that the dog had a large amount of fleas still on her. The owner is still not seeing fleas inside of the home only on the dog. The pet owner sprayed the outside of her home with pesticides and has continued to use FRONTLINE PLUS on her dogs since January but she is still seeing fleas on her dog. The dog continues scratching. The dog has not seen the veterinarian for this reaction and has not received treatment. No further medical information expected. UPDATE 12 JUL 2019: Upon internal review, corrected the dose start date field.
26-Jun-2019	UAE; 19US037170; AL; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **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	23-Jan-2019	09-Jun-2019	6 Week(s) 5 Day(s)	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On the 25 Jun 2019, a pet owner reported the following event for Lola, a 6 pound, 8 year old, spayed female, Yorkshire Terrier. 23 Jan 2019: The dog started on monthly FRONTLINE PLUS 5-22 LBS (S6107AL), with 1 dose applied topically between the shoulder blades. The owner was already seeing fleas on the dog but not inside of the home. The owner applies flea and tick products to her dogs year round but switched to FRONTLINE PLUS in January 2019. The dog is inside/outside, however she spends the majority of the time inside of the home. The dog has access to the backyard when she goes outside for her potty breaks. The backyard is fenced in, has grass, bushes and there is a small wooded area that the dog frequents on her potty breaks. The dog has a moderate amount of fleas on her. There are 2 other dogs in the home with the same issue see cases 19US037167 and 19US037172. 23 May 2019: The pet owner missed the dose in May 2019. 9 Jun 2019: The dog began scratching her hind end constantly. 23 Jun 2019: The most recent dose was applied. After she applied the product she noticed that the dog still had fleas on her, she is not seeing fleas inside of the home only on the dog. 26 Jun 2019: The owner noticed the dogs hind end had some spots that were raw with scabs from scratching. The pet owner sprayed the outside of her home with pesticides and has continued to use FRONTLINE PLUS on her dogs since January but she is still seeing fleas on her dog. The dog continues scratching. The dog has not seen the veterinarian for this reaction and has not received treatment. No further medical information expected.

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26-Jun-2019	UAE; 19US037177; -; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** - **Age:** 5.00 Year(s) **Weight:** 95 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Oatmeal Pet Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)	19-Jun-2019*	25-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy: On 26 Jun 2019, the pet owner reported the following event for Bow, a 95 pound, 5 year old, intact male, Large crossbred. 18 Jun 2019*: There were 1-3 fleas on the dog. The owner bathed the dog in an unknown oatmeal pet shampoo. 19 Jun 2019*: 1 vial of FRONTLINE PLUS DOG 89-132 LBS(R60213AR) was applied to the dog in one are between the shoulder blades. 25 Jun 2019: There were 1-3 fleas on the dog, the owner applied 1 vial to the dog. 26 Jun 2019: The owner is seeing 1-3 fleas on the dog. The owner has been treating the dog seasonally since 2014*. The dog goes out for potty breaks and recreation on 2 acres of land, urban wildlife present. The dog has no history of skin issues. There is one other dog in the home treated with FRONTLINE, the owner has not seen any fleas on this dog. There is a cat in the home treated with FRONTLINE, the owner has not seen any fleas on the cat. There are no fleas in the home. No further medical information is expected. UPDATE 22 Jul 2019: Removed erroneously entered generic name for Oatmeal pet shampoo.
26-Jun-2019	UAE; 19US037195; SC; U.S.A	**Species:** Canine **Breed:** Mixed Breeds / various **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** 5.000 - 20 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Veterinary formula flea shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Jun-2019	25-Jun-2019	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Jun 2019 the pet owner reported the following event for 2 canines as follows: Bella a 20 pound female Dachshund and Pug mix and Riley a 5 pound male Chihuahua and Dachshund mix. All other signalments are unknown. *Mar 2019: The owner began noticing fleas on the dogs and began bathing the pets every 5 days with a veterinary formula flea shampoo. 6 Jun 2019: The owner bathed the dogs again and used a flea comb to remove all of the fleas. After 8 hours the owner applied 1 vial of FRONTLINE PLUS DOG 5-22 LBS (UNKNOWN) to the skin between the shoulder blades for the first time. 25 Jun 2019: The owner began noticing fleas biting her inside the home and upon inspection saw over 100 fleas on the dogs' bellies. 26 Jun 2019: The owner applied ½ a vial of the product to each pet. There are no other pets in the home. The dogs do go outside into an unknown yard. The skin condition of the pets is unknown. No further medical information is expected. UPDATE 22 Jul 2019: Removed erroneously entered generic name for Veterinary Formula flea shampoo.
26-Jun-2019	UAE; 19US037196; MN; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 84.7 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** RECOMBITEK LYME - 2126.R0; IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 272MCG/652MG	01-Dec-2018*	26-Jun-2019	12 Week(s) 2 Day(s)	D-C	Suspected Lack of Efficacy Claim: On 26 Jun 2019, the clinic staff reported the following event for Emma, a 3 year old, 84.7 pound, female spayed Golden Retriever. She received a RECOMBITEK LYME 1 mL SC in the Left Rear on 12 Jul 2016 (42203, 4 Nov 2016), 1 Aug 2016 (42205, 10 Dec 2016), 10 Jul 2017 (42213, 16 Feb 2018), 28 Jun 2018 (42219, 8 Feb 2019). 10 Jul 2017 and 28 Jun 2018: She was diagnosed Lyme antigen negative via a routine Idexx 4Dx test. Jun 2018*: She started to use Vectra monthly. Dec 2018*: She was started on FRONTLINE PLUS(Unsubstantiated)(lot unknown) monthly. 19 Apr 2019: The animal switched back to Vectra monthly. 26 Jun 2019: She was diagnosed Lyme antigen positive via a Idexx 4Dx test. A Quant C6 has not been performed, but the blood is

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						; Vectra; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Indication not indicated / recommended)					drawn for sending. CBC, Chem 10, and UA have been ran with the following abnormalities: NPV 14.6, Cholesterol is 339, Trace protein in the urine, 25 LEU, Ketones 15 mg/dl, ERY is 250, WBC 2 per high power field, and RBC is 39 per high power field. No treatments yet started. Her current condition is ongoing. She has a pertinent medical history of on and off diarrhea from time to time, exact dates unknown. The reporter stated the dog was on HEARTGARD PLUS (272 MCG/227 MG) (lot and expiration unknown) monthly since 12 Jul 2016. No further medical information expected. UPDATE 08 Jul 2019: Per staff member, Idexx quantitative C6 test was 85 (positive > 30). Patient is being treated with a 30 day prescription of doxycycline. No additional medical information is expected. UPDATE 22 Jul 2019: Removed erroneously entered generic name for Vectra.
26-Jun-2019	UAE; 19US037209; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 7 - 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	03-Jun-2019	03-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Jun 2019, the pet owner reported the following event for a 7 to 8 pound*, intact female, Domestic Short Hair and one other cat in the household. All other signalments unknown. 3 Jun 2019: The owner was not seeing fleas on the cats. FRONTLINE PLUS CATS (lot unknown) was applied to the cat for the first time of the season. The owner has seen 1-3 fleas on the cat daily since the application. Lot is unknown because the owner discarded the package. The cats are indoor only. The owner treats seasonally. The owner is not seeing fleas in the home biting her. There is No further medical information is expected.
26-Jun-2019	UAE; 19US037222; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 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	26-Jun-2019	26-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: 26 Jun 2019: An owner reported the following event in Mozart; a 9 year old, 10 pound, neutered, male Domestic Shorthair feline. 26 Jun 2019: The owner administered FRONTLINE PLUS CATS (R40601AW) between the shoulders for the first time. The cat licked the application site and foamed at the mouth. No further medical information available.
26-Jun-2019	UAE; 19US037224; -; U.S.A	**Species:** Canine **Breed:** Canine (DO NOT USE) **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-Jan-2019*	26-Jun-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Jun 2019, the owner reported the following event for a canine with unknown signalment. Jan 2019*: One dose of FRONTLINE PLUS DOG 0-22 LBS (J63217AL) was applied topically on the neck region. 19 Jun 2019*: The most recent dose of FRONTLINE was applied. 26 Jun 2019: The owner found a nymph tick on the dog. Per the owner, ticks were not seen prior to product use. It is unknown if there are any other pets in the home. It is unknown if the dog stays indoor or outdoor. No further information at this time.

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						to Company					
23-Jun-2019	UAE; 19US037227; -; 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-Jan-2018*	02-Jan-2018*	1 Day(s)	D-C	Suspected Adverse Event: On 23 Jun 2019, the pet owner reported to a 3rd party contractor the following event for a male feline of unknown signalment. Unknown date: The cat received FRONTLINE (Unsubstantiated) (Lot Unknown). An unknown amount of time later, the cat got really sick and almost died. No other details were provided. No further medical information expected.
12-Jun-2019	UAE; 19US037242; TX; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **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	05-Jun-2019	10-Jun-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: Suspected Lack of Efficacy Claim: On 12 Jun 2019, the owner reported the following event for 1 canine, weighing 110 pounds all other signalment unknown. 5 Jun 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (R60908BR) was applied topically in between the pet's shoulder blades per the label instructions by the owner. 10 Jun 2019: A moderate- large amount of ticks were seen on the pets. The dogs are outdoor only and access to a fenced in yard. Skunks and Possums are noticed in the area. This is the first treatment of FRONTLINE PLUS and ticks were seen prior to treatment. The owner presented the dogs to the clinic and was prescribed Bravecto. 11 Jun 2019: The dog recovered. No ticks have been seen on the dogs. There is another dog within the home see additional case 19US033775. No further medical information expected.
26-Jun-2019	UAE; 19US037265; NC; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 75 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-Mar-2019*	21-Jun-2019*	31 Day(s)	D-C	Suspected Lack of Efficacy Claim and Suspected Adverse Event : On 26 Jun 2019, an owner reported the following event for two 75 pound unknown canines. One of which is a female named Missy of further unknown signalment and further signalment for the other dog is unknown. 21 Mar 2019*: The pet owner purchased a 6 pack of FRONTLINE PLUS DOG 45-88 LBS (S61111) and applied the full contents of 1 vial topically between the shoulder blades for the first time that year on each dog. 21 Apr 2019*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S61111) topically between the shoulder blades to on each dog. 21 May 2019*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S61111) topically between the shoulder blades on each dog. 21 Jun 2019*: Owner began seeing fleas on both dogs. 26 Jun 2019*: Dogs presented to veterinarian with hot spots. Veterinarian recommended using oatmeal shampoo. Veterinarian also discussed oral flea and tick products. There is also one indoor only cat in the home (reference case 19US037300). Owner usually only uses product seasonally and has used FRONTLINE PLUS for years. Apartment has been treated and owner has carpet cleaned each month. Owner also follows bathing protocols per product. No further medical information expected. UPDATE 10 Jul 2019: Dogs are indoor and outdoor. No further

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											medical information expected. UPDATE 15 Jul 2019: Hot spots were VeDDRA coded and assessed, as per original call intent.
26-Jun-2019	UAE; 19US037279; TN; 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:** Topical / Cutaneous **Was the product used ok?:** Yes	30-Apr-2019*	10-May-2019	10 Day(s)	D-A	Suspected Adverse Event: On 26 Jun 2019, the pet owner reported the following event for a feline with unknown signalment. 30 Apr 2019*: The cat began receiving FRONTLINE PLUS CATS (S40717AW) for the first time this year. The pet owner cannot remember if he has used this product previously or another topical flea prevention. 10 May 2019: The cat began experiencing seizures. The cat would go stiff, fall over, and twitch. The duration is unknown. 11 May 2019: The cat continued experiencing seizures. The cat would go stiff, fall over, and twitch. The cat bit itself and urinated on itself during these events. The duration is unknown. 12 May 2019: The cat passed away. The cat had not presented to the veterinary clinic. Another cat in the home also passed away recently, see case 19US037764. Two other cats also experienced seizures, see 19US037766 and 19US037767. The pet owner also reported that he was still seeing fleas, see case 19US037768. No further medical information expected.
26-Jun-2019	UAE; 19US037300; NC; 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	21-Mar-2019*	21-Jun-2019*	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Jun 2019, an owner reported the following event for a female unknown feline of further unknown signalment. 21 Mar 2019*: The pet owner purchased a 3 pack of FRONTLINE PLUS CATS (S41108) and applied the full contents of 1 vial topically between the shoulder blades for the first time that year. 21 Apr 2019* and 21 May 2019*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (S41108) topically between the shoulder blades. 21 Jun 2019*: Owner began seeing fleas on cat. There are also two dogs in the home (reference case 19US037265). Owner usually only uses product seasonally and has used FRONTLINE PLUS for years. Apartment has been treated and owner has carpet cleaned each month. Owner also follows bathing protocols per product. No further medical information expected. UPDATE 10 Jul 2019: The cat is indoor only. No further medical information expected.
26-Jun-2019	UAE; 19US037315; -; U.S.A	**Species:** Canine **Breed:** Retriever Labrador **Sex:** M **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	01-Jun-2019*	26-Jun-2019	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Jun 2019, the pet owner reported the following event for a 70 pound, male Labrador Retriever of unknown signalment. 1 Jun 2019*: A single dose of FRONTLINE PLUS DOG 45-88 LBS was applied topically between the shoulder blades by the animal owner. 26 Jun 2019: The owner continues to see an unknown number of fleas on the dog. Per the owner, the dog has received FRONTLINE PLUS monthly for multiple years. There are no other dogs in the home. The dog spends the majority of his time indoors but goes outside occasionally. No further information expected as the caller declined to make a report.
21-Jun-2019	UAE; 19US037320; PA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	03-Jun-2019	10-Jun-2019*	1 Week(s)	D-D	Suspected Adverse Event: On 21 June 2019, the owner reported the following event for Smokey, a 2.5 year old, 15 pound, neutered male Domestic Shorthair. 3 June 2019: The cat had fleas and one vial of FRONTLINE PLUS

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		Sex: M **Sex qualifier:** Neutered **Age:** 2.50 Year(s) **Weight:** 15 lbs				12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					CATS (FL) (S40901AW) was applied to the skin between the shoulder blades. *10 June 2019: Smokey wouldn't eat and had a fever. *12 June 2019: The cat recovered. The cat has had FL in the past at least a year without adverse symptoms. No further information available.
26-Jun-2019	UAE; 19US037380; CA; 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	21-Jun-2019	26-Jun-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Jun 2019, an animal owner reported the following event in 4 indoor cats. No further signalment provided. 21 Jun 2019: 4 felines were each administered 1 vial of FRONTLINE PLUS CATS lot, expiration unknown. Package unavailable). The animal owner did not state if the felines had doses previously. 26 Jun 2019: The animal owner is still seeing fleas. The 4 cats are indoor only. There are 3 additional cats in the household, but they are strictly outdoor as they are feral. The 3 outdoor felines are not given protection because they cant be caught. The animal owner reported that she treated the house with a powder. No further information provided nor expected.
26-Jun-2019	UAE; 19US037385; CA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 8.5 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	13-May-2019*	12-Jun-2019*	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Jun 2019, an owner reported the following event for Clove, a 6 year old (15 Jul 2012)*, 8.5 pound*, neutered female, Domestic Short Hair. 12 Apr 2018*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (R40601BW) topically between the shoulder blades monthly with a purchase of 16 doses on 12 Apr 2018*. 12 Apr 2019 and 13 May 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (R40601BW) topically between the shoulder blades 12 Jun 2019*: The owner saw 6 fleas in the home and bathed the cat. 13 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS topically between the shoulder blades. The cat is the only animal in the home. The owner is getting bit by fleas and sees fleas daily. Owner taking care of home environment daily for removal of flea eggs. Cat has not had to be seen by the veterinarian. No further medical information expected. UPDATE 10 Jul 2019: The cat is indoor only. No further medical information expected.
25-Jun-2019	UAE; 19US037389; CA; U.S.A	**Species:** Canine **Breed:** Pomeranian **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 9 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?:** Unknown	19-Jun-2019*	25-Jun-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the pet owner reported the following event for Rosie, a 3 year old, 9 pound*, intact female, Yorkshire Terrier. Unknown date: Rosie began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (lot unknown) applied topically between the shoulder blades. It is unknown how old Rosie was at the time of first application. One vial of FL+ has since been applied in the same fashion, monthly, on unknown dates, with last application having been given on an unknown date in Apr 2019 (when she ran out of product). May 2019 (unknown date): The reporter began finding an unknown quantity of fleas on Rosie. FL+ was not applied for this month due to inadequate funds to purchase more product. Throughout the month, the pet owner washed all of the dog's bedding and treated

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						to Company					her yard with an unknown flea/tick insecticide. Despite actions taken, the pet owner continued to find an unknown amount of fleas on Rosie. 18 Jun 2019*: The pet owner bathed Rosie with an unknown shampoo to get rid of the fleas on her. On approximately the same date, 3 doses of FRONTLINE PLUS DOG 5-22 LBS (S61017AL) were purchased from a local retailer (Walmart). 19 Jun 2019*: Twenty-four hours after being bathed, the reporter applied one vial of FL+ in the fashion previously described. 25 Jun 2019*: The reporter has removed 5 large fleas from the dog and continues to see an unknown number of fleas on Rosie who is also scratching as a result of the fleas. The pet owner continues to not find fleas in the home. There are two other dogs in the home that received FL+ and experienced similar events. Please see cases 19US037132 and 19US037395. The reporter was a bit challenging to get information from therefore information regarding the external environment could not be obtained. No further medical information expected.
25-Jun-2019	UAE; 19US037395; CA; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 15.000 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	19-Jun-2019*	25-Jun-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the pet owner reported the following event for Minnie Mouse, a 6 year old, 15 pound*, intact female, Yorkshire Terrier. Unknown date: Minnie Mouse began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (lot unknown) applied topically between the shoulder blades. It is unknown how old Minnie Mouse was at the time of first application. One vial of FL+ has since been applied in the same fashion, monthly, on unknown dates, with last application having been given on an unknown date in Apr 2019 (when she ran out of product). May 2019 (unknown date): The reporter began finding an unknown quantity of fleas on Minnie Mouse. FL+ was not applied for this month due to inadequate funds to purchase more product. Throughout the month, the pet owner washed all of the dog's bedding and treated her yard with an unknown flea/tick insecticide. Despite actions taken, the pet owner continued to find an unknown amount of fleas on Minnie Mouse. 18 Jun 2019*: The pet owner bathed Minnie Mouse with an unknown shampoo to get rid of the fleas on her. On approximately the same date, 3 doses of FRONTLINE PLUS DOG 5-22 LBS (S61017AL) were purchased from a local retailer (Walmart). 19 Jun 2019*: Twenty-four hours after being bathed, the reporter applied one vial of FL+ in the fashion previously described. 25 Jun 2019*: The reporter continues to find an unknown number of fleas on Minnie Mouse who is also scratching as a result of the fleas. The pet owner continues to not find fleas in the home. There are two other dogs in the home that received FL+ and experienced similar events. Please see cases 19US037132 and 19US037389. The reporter was a bit challenging to get information from therefore information regarding the external environment could not be obtained. No further medical information expected.
26-Jun-2019	UAE; 19US037430; CA; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Neutered	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn;	12-Jun-2019	26-Jun-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Jun 2019, the pet owner reported the following event for Wiley, a 16 pound, male neutered, medium crossbred. March 2019*: The dog was having an issue with fleas. The owner purchased an 8 pack of FRONTLINE PLUS DOG 5-22 LBS(S60714AX) and applied 1 vial in one area between the shoulder blades monthly. 1 Jun 2019: The dog was bathed in Dawn.

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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
		Age: - **Weight:** 16 lbs				**Route:** Topical / Cutaneous **Was the product used ok?:** Yes					12 Jun 2019: The most recent application was applied. 25 Jun 2019*:10 fleas were seen on the dog. The owner bathed the dog in Dawn to kill the fleas. 26 Jun 2019: 2 fleas were seen on the dog. The owner treats seasonally Apr.-Oct. every year. The dog goes out for potty breaks and recreation in yard where urban wildlife life are present. There are no fleas in the home. The dog has no history of skin issues. No further medical information is expected.
26-Jun-2019	UAE; 19US037486; MS; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** 5 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	14-Jun-2019*	26-Jun-2019	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Jun 2019, the pet owner reported the following event for Bailey a male intact, 5 pound, 4 year old, Chihuahua. 14 Jun 2019*: The pet owner bathed the dog with unknown shampoo. The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S62502AW) topically between the shoulder blades to the body of Bailey for the first time. 26 Jun 2019: The pet owner noticed 3 attached ticks and it is unknown if ticks were dead or alive on the body of Bailey. Bailey was in good health at time of application. Bailey was not presented to veterinarian. The home environment has been treated by pet owner. Bailey has no history of skin problems or any other issues with topical treatments. Bailey has had tick problem before in the past and it resolved. Bailey has not received any other medications or topical treatments. Bailey is indoors and outside for bathroom breaks. The current status of Bailey is unknown. No further medical information.
26-Jun-2019	UAE; 19US037487; CA; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 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?:** No (Low dose)	15-Jun-2019	16-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Jun 2019, the owner reported the following event for Junno Star, 11 year old, 45 pound, spayed female, Labrador Retriever mix canine. Unknown date : The dog started itching no fleas were noted. 15 Jun 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (L62503AL) was applied between the shoulder blades for the very first time. 16 Jun 2019*: The owner started to notice fleas on the pet and itching. 26 Jun 2019: The owner bathed the dog with flea shampoo. No fleas were at noted time of the report. There are no other pets in the household. No further medical information is expected.
27-Jun-2019	UAE; 19US037540; MD; U.S.A	**Species:** Canine **Breed:** Beagle **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 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	15-Apr-2019	25-Jun-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Jun 2019, the pet owner reported the following event for a 5 year old, 19 pound, spayed female, Beagle and miniature Dachshund mix. 2015*: The dog began receiving year-round, monthly doses of FRONTLINE PLUS DOG 5-22 LBS (P60515AL) applied topically between the shoulder blades by the animal owner with most recent applications 15 Apr 2019, 15 May 2019 and 15 Jun 2019. 25 Jun 2019: The owner noticed approximately 10 live fleas on the dog. No fleas have been observed in the home. There are no other animals in the home. The dog spends the majority of her time indoors although she goes outside for walks and spends time in a yard. The dog was not bathed within 24 hours of FORNTLINE application. No further medical infomration expected.
27-Jun-2019	UAE; 19US037566;	**Species:** Canine **Breed:** Great	1	1	0	**Product used:** FIPRONIL	01-Oct-2018*	24-Jun-2019	23 Day(s)	D-C	Suspected Lack of Efficacy Claim: On 27 Jun 2019, the pet owner reported the following event for Nala, a 18 month old (1 Dec 2017),

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	PA; U.S.A	Pyrenees **Sex:** F **Sex qualifier:** Neutered **Age:** 19.00 Month(s) **Weight:** 90 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** AFOXOLANER 136 MG CHEWABLE TABLETS; RECOMBITEK LYME - 2126.R0; IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 272MCG/652MG ; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					90 pound, spayed female, Great Pyrenees. 1 Sep 2018*: She started on a chew of NEXGARD(Unsubstantiated)(lot and expiration unknown). Owner states the dog had an unknown Lyme vaccine. Lyme negative at this time via an unknown test. 1 Oct 2018*: The dog started on FRONTLINE PLUS(Unsubstantiated)(lot unknown) for monthly use. 26 Jun 2019: She was diagnosed Lyme antigen positive via a unknown test. An unknown blood test was performed at this time. Treatments have been initiated with doxycycline. Her current condition is unknown. Case is mostly unknown as owner was driving at time of call and could not access any records. No further medical information expected. UPDATE 10 Jul 2019: Per call to clinic, The patient received a RECOMBITEK LYME(lot and expiration unknown) 1 mL SC in the left hind on 2 Nov 2018 and 1 Dec 2018. 24 Jun 2019: The dog tested Lyme antigen positive via a routine Idexx 4Dx test. The dog was asymptomatic at the time of the test. 25 Jun 2019: A Quant C6 was performed the values are currently unknown. The patient was started on Doxycycline 100 mg tablets as treatment for now. The clinic staff also stated the dog uses HEARTGARD PLUS (272 MCG/227 MG)(lot and expiration unknown) monthly, and the patient has used it since Sep 2018*. No further information is expected. UPDATE 10 Jul 2019: Per conversation with veterinarian, Idexx 4DX test performed by rescue group on 30 Aug 2018 was negative for Lyme; patient received 1 dose of NEXGARD (lot and expiration unknown) on 2 Nov 2018; result of Quant C6 test reported 28 Jun 2019 is 53 U/mL. No further medical information is expected. UPDATE 11 Jul 2019: Per medical records received on this date, there is no documentation for a Lyme test performed by the rescue group on 30 Aug 2018 as was stated by attending veterinarian via conversation on 10 Jul 2019. No further medical
27-Jun-2019	UAE; 19US037624; -; 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	26-Jun-2019	26-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 27 Jun 2019, the pet owner reported the following event for a dog of unknown signalment. 26 Jun 2019: The patient received a dose of FRONTLINE PLUS DOG 5-22 LBS(lot unknown). At the time of doing the patient jumped and ran away when the FRONTLINE hit it's skin. The owner stated the dog does this whenever someone tries to hold it still. The animal's current status is unknown. Further information is unknown as owner just wanted knowledge on product and refused further inquiry. No further medical information expected. UPDATE 27 Jun 2019: There is also a human exposure report related to this dose of FRONTLINE, see case 19US037865. No further medical information expected.
27-Jun-2019	UAE; 19US037644; CA; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown flea shampoo;	20-Jun-2019	22-Jun-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Jun 2019 the pet owner reported the following event for an unknown 6 year old, 60 pound, male large crossbred (>20 kg). All other signalments are unknown. 19 Jun 2019: The owner noticed 1-2 fleas for an unknown amount of time and bathed the dog with a flea shampoo. 20 Jun 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (R62301AR) to the skin between the shoulder blades, to the middle of the back, and to the base of the tail. It is unknown

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		Weight: 60 lbs				**Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					if this is the first application. 22 Jun 2019: The owner noticed a large amount of fleas still on the dog. The owner gave the dog a bath with a flea shampoo. *25 Jun 2019: The owner continued noticing an even larger amount of fleas on the dog. There are no other pets in the home. The dog is typically bathed on a weekly basis. The owner is not noticing an active flea life cycle in the home. The dog has access to a grassy yard. The dog frequently visits a family member's house. The dog goes to a park each evening for walks. No further medical information expected.
27-Jun-2019	UAE; 19US037661; CA; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** - **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	13-Jun-2019*	17-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 27 Jun 2019 the pet owner reported the following event for an unknown 19 pound female small crossbreed (<10 KG). All other signalments are unknown. *13 May 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 5-22 LBS (UNKNOWN) to the skin between the shoulder blades for the first time. *13 Jun 2019: The owner applied another dose. *17 Jun 2019: The owner noticed 1 piece of flea dirt on the dog and bathed the dog with an unknown shampoo. *18 Jun 2019: The owner applied another dose to the dog. *24 Jun 2019: The owner continued seeing flea dirt and a couple live fleas on the dog. It is unknown if there are any other pets in the home. It is unknown if there is indoor flea activity present. It is unknown what kind of yard if any the dog has access to. No further medical information expected.
27-Jun-2019	UAE; 19US037709; SD; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Month(s) **Weight:** 63.7 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	11-May-2019	12-May-2019	1 Day(s)	D-C	Suspected Adverse Event: On 27 Jun 2019, a veterinarian reported the following event for Ruby, a 10 month old (born 1 Jul 2018), 63.7 pound, spayed female Golden Retriever. 11 May 2019: The dog received 1 application of FRONTLINE PLUS DOG 45-88 LBS (Lot Unknown) topically between the shoulder blades. 12 May 2019: The dog did not want to move, seemed lethargic, and did not want to eat or drink. 13 May 2019: The dog presented to the clinic and had a temperature of 103.5 F. The dog's neck was red and had scabs all over it. The dog was started on prednisone. 24 Jun 2019: The dog presented to the clinic for a recheck and was doing well. No further medical information expected.
27-Jun-2019	UAE; 19US037717; NY; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 7.000 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	15-Apr-2019*	20-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 27 Jun 2019, the owner reported the following event for Lexi, a 7-8 pound*, 7 year old, female neutered, Domestic Shorthair. April 2019*: The cat started on monthly FRONTLINE PLUS CATS (Unknown) was applied topically in between the shoulder blades by the owner and no fleas were seen on the cat prior to application. An unknown time after application fleas were seen on the cat. 15 Jun 2019: The most recent vial of the FRONTLINE PLUS CATS was applied. Jun 2019*: The owner noticed a small amount of fleas on the cats. The Cat was indoor/outdoor until the owner noticed a large amount of fleas and the cat has been indoor only for 2 weeks. There are no visiting pets and no wildlife seen in the area. No further medical information is expected.
27-Jun-2019	UAE; 19US037737;	**Species:** Canine **Breed:** Siberian	1	1	0	**Product used:** FIPRONIL	24-May-2019	01-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 27 Jun 2019, the pet owner reported the following event for Marley, a 4 year old, 89 pound,

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	VA; U.S.A	Husky **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 89 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					spayed female, Siberian Husky. 24 May 2019: The patient began receiving FRONTLINE PLUS DOGS 89-132 LBS(S60906AR) and a Capstar was also given. This was the first time the animal got FRONTLINE. 1 Jun 2019*: The owner started to see fleas on the animal, at this time the animal began to become very itchy. 24 Jun 2019: The patient got a second dose of FRONTLINE PLUS DOG 89-132 LBS(S60906AR). 27 Jun 2019: The owner was still seeing fleas. The owner stated the dog is let outside about twice daily and goes out in a fenced in yard. The owner stated she is seeing fleas in the household, but not on her person. She stated she sees about 1-5 fleas daily in general. There have been no treatments for the household, or any further treatments for the dog. The patient's current condition is ongoing. There a total of 1 canine in the household. No further medical information expected.
27-Jun-2019	UAE; 19US037741; CA; 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	24-Jun-2019*	25-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Jun 2019, the clinic staff reported the following event for a canine (all other signalments unknown). 24 Jun 2019: One vial of FRONTLINE PLUS (product unsubstantiated) (lot unknown) was applied topically at an unknown location. 25 Jun 2019*: The owner continued to notice fleas. 27 Jun 2019: The issue is still ongoing. It is unknown if the dog recieved the product before. The pet's environment is unknown. It is unknown if there are any other pets in the environment. No further medical information is expected.
27-Jun-2019	UAE; 19US037749; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** - **Age:** - **Weight:** Unknown	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?:** Unknown to Company	01-Jun-2019*	05-Jun-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Jun 2019, a pet owner reported the following event for 5 canines of unknown signalment. 2015*: The dog began using FRONTLINE PLUS DOG 45-88 LBS (lot unknown). Jun 2019*: The owner applied the most recent dose and still saw fleas 4 days later. The owner applied a double dose to one of the dogs. The dogs are mainly indoors but do go outside on occasion. All further details are unknown as the owner refused to report. No further medical information expected.
27-Jun-2019	UAE; 19US037750; TN; U.S.A	**Species:** Canine **Breed:** Dachshund **Sex:** M **Sex qualifier:** - **Age:** 5.00 Month(s) **Weight:** 5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	15-Jun-2019	27-Jun-2019	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Jun 2019, the pet owner reported the following event for Tyrion, a 5 month old 5 pound intact male Dachshund. 15 Jun 2019: The pet owner applied a dose of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) down to the skin between the shoulder blades for the first time. The dog did not have fleas at that time. The dog went swimming about 23 hours after application. 27 Jun 2019: The pet owner found a moderate amount of fleas on the dog. There are no fleas in the home and no other pets in the home. The pet owner has not treated the home but has washed the dog bedding. The dog goes outside but there are not a lot of

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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?: Yes					trees outside. No further medical information expected.
27-Jun-2019	UAE; 19US037760; IN; U.S.A	**Species:** Canine **Breed:** Rottweiler **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 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	13-Jun-2019*	27-Jun-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Jun 2019, the pet owner reported the following event for Zeek, a male neutered, 75 pound, 1 year old, Rottweiler. 13 Jun 2019*: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (S61111AR) topically to skin between the shoulder blades of Zeek for the first time. 27 Jun 2019: The pet owner noticed 1-5* fleas on the body of Zeek. Zeek was in good health at time of application. Zeek was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has seen fleas in the home. Zeek has no history of skin problems or any other issues with topical treatments. Zeek has not had flea problem before in the past. Zeek has not received any other medications or topical treatments. Zeek has not been bathed. Zeek is indoors and outside in fenced yard. The current status of Zeek is unknown. No further medical information.
26-Jun-2019	UAE; 19US037764; TN; 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:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	30-Apr-2019*	17-May-2019	17 Day(s)	D-A	Suspected Adverse Event: On 26 Jun 2019, the pet owner reported the following event for a feline with unknown signalment. 30 Apr 2019*: The cat received FRONTLINE PLUS CATS (S40717AW) for the first time this year. Fleas were seen prior to product application. The pet owner cannot remember if he has used this product previously or another topical flea prevention. 17 May 2019: The cat began experiencing seizures. The cat would go stiff, fall over, and twitch. The duration is unknown. 18 May 2019: The cat continued experiencing seizures. The cat would go stiff, fall over, and twitch. The duration is unknown. The cat passed away. The cat had not presented to the veterinary clinic. There were a total of 15 cats in the home. Another cat in the home also passed away recently, see case 19US037279. Two other cats also experienced seizures, see 19US037766 and 19US037767. The pet owner also reported that he was still seeing fleas, see case 19US037768. No further medical information expected.
26-Jun-2019	UAE; 19US037766; TN; 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	30-Apr-2019*	26-Jun-2019	8 Week(s) 1 Day(s)	D-B	Suspected Adverse Event: On 26 Jun 2019, the pet owner reported the following event for a feline with unknown signalment. 30 Apr 2019*: The cat received FRONTLINE PLUS CATS (S40717AW) for the first time this year. Fleas were seen prior to product application. The pet owner cannot remember if he has used this product previously or another topical flea prevention. 26 Jun 2019: The cat experienced one seizure. The cat went stiff, fell over, and was twitching. The cat bit himself during the event. The event lasted 10-20 seconds. The cat has not presented to the veterinary clinic. There were a total of 15 cats in the home. Two cats in the home passed away recently, see case 19US037279 and 19US037764. Another cat also experienced seizures, see 19US037767. The pet owner also reported that he was still seeing fleas, see case 19US037768. No further medical information expected.
26-Jun-2019	UAE; 19US037767; TN; U.S.A	**Species:** Feline **Breed:** Feline (unknown)	1	1	0	**Product used:** FIPRONIL 10%/S	30-Apr-2019*	23-Jun-2019	7 Week(s) 5 Day(s)	D-C	Suspected Adverse Event: On 26 Jun 2019, the pet owner reported the following event for a feline with unknown signalment. 30 Apr 2019*: The cat began receiving FRONTLINE PLUS CATS

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		Sex: U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					(S40717AW) for the first time this year. The pet owner cannot remember if he has used this product previously or another topical flea prevention. 23 Jun 2019: The cat began experiencing seizures. The cat would go stiff, fall over, and twitch. The duration of the event is unknown. The cat has not presented to the veterinary clinic. Two cats in the home passed away recently, see cases 19US037279 and 19US037764. Another cat also experienced seizures, see 19US037766. The pet owner also reported that he was still seeing fleas, see case 19US037768. No further medical information expected.
26-Jun-2019	UAE; 19US037768; TN; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	13	13	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-Apr-2019*	26-Jun-2019*	8 Week(s) 1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Jun 2019, the pet owner reported the following event for 13 felines with unknown signalment. 30 Apr 2019*: The cats received FRONTLINE PLUS CATS (S40717AW) for the first time this year. The pet owner cannot remember if he has used this product previously or another topical flea prevention. The pet owner purchased several packages at once from PetSense. The product is applied directly on the skin between the shoulder blades. 26 Jun 2019*: The owner noticed fleas. The cats are indoors only. Fleas have been noticed in the home environment as well as on the cats. Family members are being bitten. The cats have not presented to the veterinary clinic. Their current condition is ongoing. There was a total of 15 felines in the household. Two cats in the home passed away recently, see cases 19US037279 and 19US037764. Two other cats also experienced seizures, see 19US037766 and 19US037767. No further medical information expected.
27-Jun-2019	UAE; 19US037782; CA; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 6 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Bravecto; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	10-May-2019*	06-Jun-2019*	27 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Jun 2019, the pet owner reported the following event for Coco, a female spayed, 6 pound, 3 year old, Yorkshire Terrier. Unknown dates: The pet owner administers Bravecto. 10 May 2019*: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S63009BL) topically to skin between the shoulder blades of Coco for the first time. 6 Jun 2019*: The pet owner noticed 2-3* fleas on the body of Coco. Coco was in good health at time of application. Coco was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen any fleas in the home. Coco has no history of skin problems or any other issues with topical treatments. Coco has not had flea problem before in the past. Coco has not received any other topical treatments. Coco has not been bathed. Coco is indoors and outside for walks. The current status of Coco is unknown. No further medical information.
27-Jun-2019	UAE; 19US037788; -; U.S.A	**Species:** Canine **Breed:** Weimaraner **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s)	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	26-Jun-2019	26-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 27 Jun 2019, the owner reported the following event for Gus, a 85 pound, 2 year old*, neutered male Weimaraner. 26 Jun 2019: One dose of FRONTLINE PLUS DOG 45-88 LBS (S61202AX) topically in between the shoulders. The owner noticed later that night, that Gus' skin was purple and sticky at the FRONTLINE application site. The owner washed the area with mild

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		Weight: 85 lbs				products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					soap and water. 27 Jun 2019: The area is no longer sticky, but remains purple. There is no pain or tenderness associated with the area. There were no other symptoms noticed. The owner is adamant that the pet did not rub on anything. The pet has recieved the product monthly since 2018 with no prior issues. No further information at this time.
27-Jun-2019	UAE; 19US037789; 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:** unspecified shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	05-Jun-2019	27-Jun-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Jun 2019 an animal owner reported the following event in 2 dogs. All other signalment not reported. 04 Jun 2019: The 2 canines were bathed with unspecified shampoo. 05 Jun 2019: The 2 canines were each administered 1 vial of FRONTLINE PLUS 89-132 LB (P004293). No fleas at time of administration. 27 Jun 2019: Animal owner was seeing 4 or 5 fleas on each canine. Each canine was administered 1 vial of FRONTLINE PLUS. No other pets in the household. The canines have access to outdoors. No stray or wildlife exposure. No fleas seen in the environment. No further information provided nor expected.
27-Jun-2019	UAE; 19US037794; PA; U.S.A	**Species:** Canine **Breed:** Border Collie **Sex:** F **Sex qualifier:** Neutered **Age:** 2.50 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 product used ok?:** Yes	13-Jun-2019	27-Jun-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Jun 2019, the owner reported the following event for Maize, a 30 pound, 2.5 year old, female neutered, Border Collie Mix. 9 May 2019: One vial of the FRONTLINE PLUS DOG 23-44 LBS (S61009AL) was applied topically in between the shoulder blades by the owner. 13 Jun 2019: One vial of the FRONTLINE PLUS DOG 23-44 LBS (S61009AL) was applied topically in between the shoulder blades by the owner. 27 Jun 2019: The owner noticed 2 fleas on the pet. The dog is indoor/outdoor. The dog has access to a fenced in yard. This is the first time the owner has noticed fleas on the pet. The owner has used FRONTLINE since May 2019. There are 2 cats in the home that are treated with FRONTLINE see additional case 19US038097. No further medical information is expected.
27-Jun-2019	UAE; 19US037795; 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?:** Yes	13-Jun-2019	27-Jun-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim:On 27 Jun 2019, the owner reported the following event for 2 unknown felines, all other signalment unknown. 9 May 2019: One vial of the FRONTLINE PLUS CATS (S61009AL) was applied topically in between the shoulder blades by the owner. 13 Jun 2019: One vial of the FRONTLINE PLUS CATS (S61009AL) was applied topically in between the shoulder blades by the owner. 27 Jun 2019: The owner noticed 2 fleas on the pets. The cats are strictly indoor. The dog has access to a fenced in yard. This is the first time the owner has noticed fleas on the pets. The owner has used FRONTLINE since May 2019. There are is 1 dog in the home that is treated with FRONTLINE see additional case 19US037794. No further medical information is expected.
25-Jun-2019	UAE; 19US037818; PA; U.S.A	**Species:** Feline **Breed:** Domestic Longhair	1	1	0	**Product used:** FIPRONIL 10%/S	25-May-2019	10-Jun-2019*	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Jun 2019, the animal owner reported the following event for Nana, a 2 year old, 18 pound, spayed female, Domestic Longhair.

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		(Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 18 lbs				METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** PO-Oral **Was the product used ok?:** Yes					25 May 2019: The animal received her monthly dose of FRONTLINE PLUS CATS (lot unknown). This was applied correctly by the owner and Nana has been on FRONTLINE monthly since 25 Feb 2019. 10 Jun 2019*: The owner started to noticed fleas on the animal, and that the animal had been itching due to this. There were no other products given at the same time to the animal, and the owner stated the animal is never bathed. The owner stated she is not seeing fleas on herself or in the house. She has been vacuuming daily to help prevent fleas. Her yard is in a wooded area and the cat does not go outside. The owner stated she is seeing about 10 fleas daily. The animal has no prior reactions to any other drugs, and is currently not gotten any further treatments for the fleas. The animal's current condition is ongoing. There a total of 1 canine and 1 feline in the household. Please see case 19US036788 for the canine's event. No further medical information expected.
28-Jun-2019	UAE; 19US037860; -; 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	27-Jun-2019*	27-Jun-2019*	0 Day(s)	D-C	Suspected Adverse Event: On 28 June 2019, the owner reported the following event for a dog with unknown signalment. *Unknown date; The dog received one application of FRONTLINE PLUS DOG 89-132 (lot unknown). *Unknown date: The dog started to develop respiratory issues and a loss of appetite. The owner declined the report, no further information available.
28-Jun-2019	UAE; 19US037910; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Lactating **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	28-Jun-2019*	28-Jun-2019*	0 Day(s)	D-C	Suspected Adverse Event: On 28 Jun 2019, the pet owner reported the following event for a lactating, intact feline of further unknown signalment. 28 Jun 2019*: The queen received unknown FRONTLINE (lot unknown) (product unsubstantiated) applied topically in an unknown location. An unknown duration following product application, she began foaming at the mouth and is described as "doing a little twitching here and there". At the time of product application, the queen was nursing two 3 week old kittens who have fleas. Further details cannot be obtained as they were refused by the reporter. No further medical information expected.
28-Jun-2019	UAE; 19US037922; NE; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 15.00 Month(s)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown	27-Jun-2019	28-Jun-2019	1 Day(s)	D-C	Suspected Adverse Event: On 28 Jun 2019, the veterinarian reported the following event for George, a male, neutered Domestic Shorthair of unknown body weight. Unknown date: The cat began receiving FRONTLINE PLUS CATS (Lot S40502AX). The product application info is unknown. 27 Jun 2019: The most recent date of application. 28 Jun 2019: Per the pet owner, the cat was not acting himself, since he normally wakes the owner each morning, and he did not this morning. The cat was dropped off at the veterinary clinic. The cat seemed normal to the veterinarian, but did mention he was

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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				**Was the product used ok?:** Unknown to Company					shaking and panting inside the carrier. It is unknown if any diagnostics were performed or treatments provided. The cat's current condition is unknown. No further medical information expected. UPDATE 01 July 2019: Contacted the clinic. A CBC showed mild dehydration and a stress leukogram, and a chemistry panel was within normal limits on 29 June 2019. George was treated with subcutaneous fluids and a bath. He recovered on or about 29 June 2019.
27-Jun-2019	UAE; 19US037942; MN; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **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?:** Unknown to Company	27-Jun-2019	27-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 27 June 2019, the owner reported the following suspected adverse event to Safety Call International for Kit Weeks, a 2 year old, 10 pound, neutered male Domestic Mediumhair. 27 June 2019: One vial of FRONTLINE PLUS CATS (FL) (S40606AW) was applied topically to the skin between the shoulder blades around 7:45. The cat shook to get the product off and around 8:45 the cat licked the application site. The cat started to drink water and went into hiding. He eventually came out and started to act normal. This was the second application of FL. No further medical information expected.
28-Jun-2019	UAE; 19US037946; CA; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Neutered **Age:** 9.50 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?:** Yes	24-Jun-2019	25-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Jun2019, the pet owner reported the following event for Bentley, a male neutered, 90 pound, 9.5 year old, Retriever (Golden) . Unknown dates: Owner applies FRONTLINE PLUS DOG 89-132 LBS (S62408AX) on seasonal basis monthly. 24 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 89-132 LBS topically to skin between the shoulder blades of Bentley monthly on seasonal basis. 25 Jun 2019: The pet owner noticed unknown amount fleas on the body of Bentley. Bentley was in good health at time of application. Bentley was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen any fleas in the home. Bentley has no history of skin problems or any other issues with topical treatments. Bentley has not had flea problem before in the past. Bentley has not received any other medications or topical treatments. Bentley has not been bathed. Bentley is indoors and outside for walks. The current status of Bentley is unknown. No further medical information.
28-Jun-2019	UAE; 19US037952; WV; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 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 / Cutaneous **Was the product used ok?:** Yes	15-Jun-2019	25-Jun-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim and Supsect Adverse Event : On 28 Jun 2019 an animal owner reported the following event in Garfield, a 12 year old, 11 pound, male neutered, Polydactyl. 15 Jun 2019: 1 vial of FRONTLINE PLUS CATS (lot, expiration unknown as owner was elderly and could not read) was applied in between the feline's shoulder blades for the first time. Fleas were seen at time of administration. 25 Jun 2019: The feline presented for nausea. Fleas were seen at time of exam. 28 Jun 2019: The feline presented for itching. Fleas were seen at time of exam. The feline was prescribed Bravecto. The cat is indoor and outdoor. No other pets in the household. 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
28-Jun-2019	UAE; 19US037968; VA; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 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?:** Yes	07-May-2019	21-May-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Jun 2019, a pet owner reported the following event for Diesal, an 11 year old, 110 pound, neutered male Large Crossbred Canine. 2014*: The dog began receiving monthly, year round FRONTLINE PLUS DOG 89-132 (S62006AX) topically between the shoulder blades in one spot, with a 3 pack purchased from Walmart in Apr 2019. 7 May 2019: The dog received 1 application of FRONTLINE. 21 May 2019*: The dog was scratching more than usual and the owner noticed a few live fleas near the dog's tail. 7 Jun 2019: The dog received 1 application of FRONTLINE. The owner found 1 live tick crawling on the dog and removed it. 26 Jun 2019: The owner found 1 live tick on the dog, embedded in his groin. The owner removed the tick. The owner is not seeing fleas in the home and is not getting bit. The yard is fenced in and the owner does not treat the yard. There are no other pets in the home. The owner was concerned about this FRONTLINE being a bad batch. No further information expected.
28-Jun-2019	UAE; 19US037997; TX; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 45 - 88 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	18-Apr-2019	28-Jun-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Jun 2019, the office manager reported the following event for 3 canines, between 3-9 years of age, and weighing 45-88 pounds all other signalment unknown. 18 Apr 2019: One vial of the FRONTLINE PLUS DOG 45-88 LBS (R61513AR) was applied topically in between the shoulder blades by the owner. 18 May 2019: One vial of the FRONTLINE PLUS DOG 45-88 LBS (R61513AR) was applied topically in between the shoulder blades by the owner. 18 Jun 2019: One vial of the FRONTLINE PLUS DOG 45-88 LBS (R61513AR) was applied topically in between the shoulder blades by the owner. The owner noticed a small amount of fleas. The dogs are indoor mostly and go outside for potty breaks in a large fenced in yard. Wildlife has not been seen within the area. It is unknown if there have fleas have been seen in the home. The owner has used FRONTLINE on a year round basis. This is the only pet within the home. No further medical information is expected.
28-Jun-2019	UAE; 19US038007; SD; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	5	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-Jun-2019	21-Jun-2019*	4 Day(s)	D-D	Suspected Adverse Event Claim: On 28 Jun 2019, the pet owner reported the following event for 2 cats, other signalment unknown. 17 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S40606AW) topically to skin between the shoulder blades of the cats for the first time. 21 Jun 2019*: A total of 5 cats received the product however the pet owner noticed 2 of the cats developed raw sores around their necks near application site while the remaining 3 cats have had no issues. The cats were in good health at time of application. The cats were not presented to veterinarian. The cats have no history of skin problems or any other issues with topical treatments. The cats have no history of drug or vaccine reactions. The cats have not been bathed. The cats are indoors only. The cats are at home with ongoing issue. No further medical information.
28-Jun-2019	UAE; 19US038015; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown)	1	1	0	**Product used:** FIPRONIL 10%/S	01-Jun-2019	13-Jun-2019	12 Day(s)	D-D	Suspected Adverse Event: On 28 Jun 2019, Animal owner reported the following event for her cat. All signalment is unknown. 01 Jan 2019: Started monthly FRONTLINE PLUS CATS (Lot

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		Sex: U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					unknown) topically between the shoulder blades for pre-existing fleas. 01 Jun 2019: A dose was applied topically between the shoulder blades. 13 Jun 2019: The pet owner noticed sores on the cats chin and the cat is scratching a lot. The owner has not seen fleas on her cat since the first application. There are no other animals in the house. The cat has not been seen by a vet for further examination. No further information expected.
28-Jun-2019	UAE; 19US038029; -; U.S.A	**Species:** Canine **Breed:** Dachshund **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 14 - 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?:** Yes	14-Mar-2019*	15-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Jun 2019, the owner reported the following event for a 14 pound and 18 pound Dachshund (all other signalments unknown). Unknown date: Started on monthly doses of FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown) topically between the shoulder blades. Mar 2019: The owner started seeing fleas on the dogs. 14 Jun 2019*: Most recent dose of FRONTLINE was applied. 15 Jun 2019*: The owner continued seeing fleas on the dogs. The owner is not seeing fleas in the house. The dogs go outside for potty breaks in a fenced in yard with trees. No further medical information expected.
28-Jun-2019	UAE; 19US038053; NY; U.S.A	**Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** - **Age:** 14.00 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?:** Unknown to Company	28-May-2019	27-Jun-2019	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Jun 2019 the pet owner reported the following event for Peetie, a 14 year old (born 9 Aug 2004), 19 pound, intact male Miniature Poodle. 28 May 2018: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown), 1 dose, topically, to an unknown application site for the first time in 2019. 27 Jun 2019: The pet owner noted a tick on the canine and applied the second dose. 28 Jun 2019: The canine presented to the clinic where the tick was removed. The canine spend the majority of the time inside the home with access to wooded areas outside. There is one rabbit and one parrot in the household. No further medical information is expected.
28-Jun-2019	UAE; 19US038056; SC; U.S.A	**Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** - **Age:** 2.00 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	23-May-2019	28-May-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Jun 2019, the pet owner reported the following event for Cali, a female intact, non pregnant non-lactating, 54 pound, 2 year old, Pit Bull. 23 May 2019 The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS(S62111AL) topically to skin between the shoulder blades to the body of Cali for the first time. 28 May 2019*: The pet owner noticed 10* fleas on the body of Cali. 23 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS topically to skin between the shoulder blades to the body of Cali monthly. Cali was in good health at time of application. Cali was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has not seen any fleas in the home. Cali has no history of skin problems or any other issues with topical treatments. Cali has not had flea problem before in the past. Cali has not received any other medications or topical treatments. Cali has not been bathed. Cali is indoors and outside for walks. The

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											current status of Cali is unknown. No further medical information.
28-Jun-2019	UAE; 19US038077; TX; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 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-May-2019	10-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 28 Jun 2019, the pet owner reported the following event for Charlie, a male neutered, 15 pound, 7 year old, Small crossbred. 27 May 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) topically to skin between the shoulder blades to the body of Charlie for the first time. 10 Jun 2019: The pet owner noticed 15+ fleas on the body of Charlie. 27 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS topically to skin between the shoulder blades to the body of Charlie. Charlie was in good health at time of application. Charlie was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen any fleas in the home. Charlie has no history of skin problems or any other issues with topical treatments. Charlie has not had flea problem before in the past. Charlie has not received any other medications or topical treatments. Charlie has not been bathed. Charlie is indoors and outside for walks. The current status of Charlie is unknown. No further medical information.
29-Jun-2019	UAE; 19US038092; TN; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(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	27-Jun-2019	28-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 28 Jun 2019, the pet owner reported the following event for Daisy, a female spayed, 14 pound, 8 year old, Shih Tzu. 27 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (S62502AW) topically to skin between the shoulder blades of Daisy for the first time. 28 Jun 2019: The pet owner noticed Daisy experience lethargy not wanting to eat and vomited around 6p*. Daisy is currently at home with ongoing issue. Daisy was in good health at time of application. Daisy was not presented to veterinarian. Daisy has not had any other products at the same time as the FRONTLINE PLUS DOG application. Daisy does not have history of drug or vaccine reactions. The pet owner is not sure if she has used FRONTLINE PLUS DOG in the past. No further medical information.
27-Jun-2019	UAE; 19US038094; SD; U.S.A	**Species:** Canine **Breed:** English Bulldog **Sex:** M **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** 62.7 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-Jan-2019*	02-Jan-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 27 Jun 2019, a veterinarian reported the following event for Mr. Pickles, a 4 year old (born 8 Apr 2014), 62.7 pound, intact male English Bulldog. Unknown Date: The dog received 1 dose FRONTLINE (Unsubstantiated) (Lot and Expiration Unknown) topically in an unknown location. Unknown Date: The dog had sores on his back where the FRONTLINE was applied. It is unknown if the dog had ever received the product before and it is unknown if any treatments were provided. No further information expected.
25-Jun-2019	UAE; 19US038110; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON	01-Apr-2019*	02-Jun-2019*	8 Week(s) 6 Day(s)	D-C	Suspected Adverse Event: On 25 Jun 2019, the pet owner reported the following event for Kohl a 2 year old, 17 pound, neutered male, unknown breed. 2017*: The patient received his first dose of FRONTLINE PLUS CATS(lot unknown). Some unknown time after the use of the

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		Neutered **Age:** 2.00 Year(s) **Weight:** 17 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					FRONTLINE the cat began to have unspecified urinary tract issues. It was not treated at this time. 1 Apr 2019*: The animal received another dose of FRONTLINE PLUS CATS. 2 Apr 2019*: The cat developed another unspecified urinary tract issue. This was treated by switching the cat to a Royal Canin diet for unspecified urinary tract issues. The animal is current still using the food to help prevent and control the issues. The owner stated the animal has been on FRONTLINE PLUS with no other issues since 2017*. This cat had a subsequent event reported for FRONTLINE GOLD, see case 19US005932 further medical information expected.
17-Jun-2019	UAE; 19US038569; CA; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** Neutered **Age:** 15.00 Month(s) **Weight:** 14 lbs	1	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	01-May-2019	27-May-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the owner reported the following event for Lucy, 15 month old, 14 pound, spayed female, Maltese canine. 1 May 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S60401AX) was applied between the shoulder blades. 15 May 2019: A few sprays of FRONTLINE SPRAY (lot unknown) were applied throughout the pets body. 27 May 2019: The owner found fleas on the pet. 1 Jun 2019: The flea issue sporadically continued. Another vial was applied. 13 Jun 2019: The owner found a tick attached to the pet. The tick was removed and still alive. The dog has access to an open and treated yard. The dog has received the product monthly since 1 Oct 2018 with a sporadic issue with fleas. No further medical information is expected.
19-Jun-2019	UAE; 19US038868; OH; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 98 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*	01-Apr-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 19 Jun 2019, a pet owner reported the following event for Louie, a 3 year old (born 26 Jul 2015), 98 pound, neutered male Golden Retriever/Standard Poodle mix. Apr 2016*: The dog began receiving applications of FRONTLINE PLUS DOG 89-132 LBS (Lot and Expiration Unknown) seasonally between the shoulder blades in one spot. Unknown Dates: After an unknown number of the monthly applications, the dog experienced a few episodes of diarrhea. These episodes would last for 1-2 days and then resolve. The owner could not recall which months the diarrhea occurred. This dog has since reacted to FRONTLINE, see case 19US035394. No further medical information expected.
19-Jun-2019	UAE; 19US038869; SD; U.S.A	**Species:** Feline **Breed:** Ragdoll **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 14 - 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	01-Dec-2018*	01-Dec-2018*	0 Day(s)	D-D	Suspected Adverse Event: On 19 Jun 2019, the pet owner reported the following event for Mitsy, a 14 to 15 pound*, 6 year old, female spayed,Ragdoll. 1 Dec. 2018*: 1 vial of FRONTLINE PLUS CATS (lot and expiration unknown) was applied to the cat in one area between the should blades monthly. Immediately after the FRONTLINE was applied the cat would act frantic and then become lethargic. She recovered an unknown time after the application. The owner has switched to FRONTLINE GOLD, see case 19US35658. It is unknown how long the cat has been on FRONTLINE, owner applied on the 1st of every month. No further medical information is expected.

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24-Jun-2019	UAE; 19US039784; MI; 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	01-Jun-2019	21-Jun-2019	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, the owner reported the following event for a feline (all other signalments unknown). 1 Jun 2019: One vial of FRONTLINE PLUS CATS (S40503AX) was applied between the shoulder blades. 21 Jun 2019: The owner noticed the cat itching and fleas. 24 Jun 2019: The issue is still ongoing. No fleas were noted in the household. The cat has access to a fenced in yard. The cat has received the product on 1 May 2019 with no prior issue. There is a dog in the household also experiencing an issue (see case 19US036771). No further medical information is expected.
28-Jun-2019	UAE; 19US040159; CA; U.S.A	**Species:** Canine **Breed:** Boxer **Sex:** M **Sex qualifier:** Unknown **Age:** - **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	09-Jun-2019	28-Jun-2019	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Jun 2019, an owner reported the following event for Dexter, a 90 pound, male, Boxer of further unknown signalment. 09 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 89-132 LBS (S61111AR) topically between the shoulder blades for the first time. 28 Jun 2019: The owner found several fleas on the dog. The dog is the only pet in the home and it is indoor/outdoor. Owner is undergoing cancer treatments and can't treat the inside of the home. Reference case 19US037951 for use of FRONTLINE GOLD DOG 89-132 LBS (lot unknown). No further medical information expected.
02-Apr-2019	UAE; 19ZA000101; ECP; South Africa	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 5.6 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?:** Yes	18-Mar-2019	01-Apr-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy: as reported by the owner, a dog, female Yorkshire Terrier, neutered, 10 years old, 5.6 kg, in an unknown health condition, received FRONTLINE PLUS DOG S (BN and exp dat unknown), route and dose unknown, by owner on 18 MAR 2019. The dog is still infested with fleas 2 weeks after treatment (01 APR 2019 was chosen by default). The owner has used different products, also Seresto collar. She acknowledges the problem to be an infested home. She has been using Frontline for a long time. The event is ongoing. This is the extent of information available.
15-Apr-2019	UAE; 19ZA000109; ECP; South Africa	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 3 Kilograms	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?:** Yes	14-Feb-2019*	04-Apr-2019	0 Day(s)	D-D	Suspected Lack of Efficacy: as reported by the owner, 2 domestic cats, neutered females, 1 year old and 5 years old, both 3 kg, in an unknown health condition, received FRONTLINE PLUS CATS (BN and exp date unknown), route and dose unknown, three times in 7 weeks, by owner, with last treatment on 04 APR 2019. Cats are still scratching and the owner sees live fleas. They were housed at the SPCA for 10 days when she went away but they were scratching and had fleas before they went already. She also said the Frontline had no smell like previously when she used it. The evolution of the event is unknown. This is the extent of information available.
20-May-2019	UAE; 19ZA000116; KZN; South Africa	**Species:** Canine **Breed:** Retriever (Golden)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	18-May-2019	18-May-2019	0 Day(s)	D-D	As reported by the owner, 3 dogs, female Husky x Collie, 30 kg, 5 yrs old; female Labrador, 25 kg, 9 yrs old and male mini Yorkshire terrier, 2 kg, 6 yrs old, all intact, in an unknown health condition, received FRONTLINE PLUS DOGS (BN and exp date unknown),

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		Sex: F **Sex qualifier:** - **Age:** 9.00 Year(s) **Weight:** 25 kg				9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Yes					route and dose unknown, on 18 MAY 2019 by owner as they were starting scratching. After treatment they never stopped scratching and she saw live fleas on them. The dogs were treated with Frontline before but the owner then switched over to NexGard and Bravecto for some time. Then there was no treatment for a while. The owner also has 3 cats that do not get treated as they have no fleas. The evolution of the event is unknown. This is the extent of information available.
27-May-2019	UAE; 19ZA000120; KZN; South Africa	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 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	01-May-2019*	01-May-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the owner, 3 of 4 cats, domestic shorthair crossbreed, males neutered, aging from 6 to 10 years old, weighting from 5 to 8 kg, in unknown health conditions, were treated with FRONTLINE PLUS (BN and exp date unknown) during the first week of MAY (01 MAY 2019 was chosen by default). On an unknown date (01 MAY 2019 was chosen by default), the owner still saw tiny fleas on the ears. The cats used to sleep in bushes around the office and to be feed by office 's people. They are also treated infrequently. The evolution of the event is unknown. This is the extent of information available.
03-May-2019	UAE; 19ZA000135; WCP; South Africa	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 4.5 kg	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?:** Yes	26-Mar-2019	16-Apr-2019*	3 Week(s)	N/A	As reported by the owner, a dog, male Yorshire terrier, neutered, 7 years old, 4.5 kg, in an unknown health condition, received FRONTLINE PLUS DOGS S (BN and exp date unknown), route and dose unknown, on 26 MAR 2019 by owner. Three weeks after treatment the dog still had 3 fleas especially around the anal area. The owner has totally 2 dogs. The flea treatment program alternates between FRONTLINE PLUS and ADVOCATE every 3 weeks due to severe flea problem. The evolution of the event is unknown. This is the extent of information available.

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Worldwide Adverse Event Reports Involving - Human Cases
Reporting Period: 01-Apr-2019 to 01-Jul-2019 [1]

Date case Received	Case type; Case Reference; 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-Jun-2019	UHAE; 19BE000079; -; Belgium	**Sex:** F **Sex qualifier:** Unknown**Age:** 17.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** intraocular **Was the product used ok?:** No (Human exposure (Off label use))	29-Apr-2019	29-Apr-2019	<=2 minutes	H-D	Poison Centre: call from a family member on a woman (17 years) showing eye irritation afer eye contact with FRONTLINE spot-on katten. There was no delay between the phone call and the incident. Local decontamination was advised and go to an ophtalmologist if symptoms persist. Local decontamination was advised.
04-Apr-2019	UHAE; 19DK000033; -; Denmark	**Sex:** F **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** auricular **Was the product used ok?:** No (Species not indicated / recommended)	2018*	2018	0 Day(s)	H-E	Asymptomatic human exposure. As seen on Social Media, an adult female veterinarian posted on Facebook that after cleaning the ears on a cat with ear mites she got some infected ear wax on her neck. In the evening it was a scratching noise in her ear. She tried Canaural without effect and then applied FRONTLINE (product unsubstantiated, dose and strength unkonwn) in the ear and the scratching stopped immediately.
02-May-2019	UHAE; 19FR000558; -; France	**Sex:** F **Sex qualifier:** Unknown**Age:** 71.00 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?:** No (Human exposure (Off label use))	18-Mar-2019	18-Mar-2019	0 Day(s)	H-D	FR-ANMV-19 CPVL 00538: T0: a woman accidentally sprayed FRONTLINE SPOT ON CHAT on her hands. Intense washing. T+10min: she displayed pruritus and paresthesia. Duration of reaction: < or = 30 minutes. Duration of reaction (precision): Unknown (10 min). Treatment of SAR: washing. Outcome of SAR: Unknown.
12-Jun-2019	UHAE; 19TH000008; -; Thailand	**Sex:** F **Sex qualifier:** -**Age:** - **Weight:** -	-	-	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	10-Jun-2019	N/A	N/A	H-E	The Pet Owner consulted about safety of Frontline plus size S (< 10kg). She informed me that she accidentally got a drop of the Frontline Plus solution on her hand while applying it on her dog. She's around 6-7 weeks pregnant and wondering if she should be concerned. She wash her hands afterwards though. No symptoms were reported.

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						Was the product used ok?: No (Human exposure (Off label use))					
01-Apr-2019	UHAE; 19US016023; CO; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 60.00 Year(s) **Weight:** 159.000 Pounds	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure (Off label use))	01-Apr-2019	01-Apr-2019	N/A	H-E	Human Exposure: On 1 Apr 2019, the following human exposure inquiry was reported to Safety Call International (SCI) by the pet owner for themselves, a 60 year old, 159 pound, female human of further unknown signalment. 1 Apr 2019: The pet owner accidentally splashed a drop of the FRONTLINE PLUS DOG 45-88 LBS (F60913AR) into her left eye as she snapped the tip to open. After exposure she rinsed her eye for 5 minutes. The pet owner was asymptomatic. No further medical information expected.
03-Apr-2019	UHAE; 19US017018; CA; U.S.A	**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?:** No (Human exposure (Off label use))	03-Apr-2019*	03-Apr-2019	0 Day(s)	H-E	Human Exposure: On 3 Apr 2019, the following human exposure was reported by the pet owner for himself, signalment unknown. 3 Apr 2019: While opening the packaging for a vial of FRONTLINE PLUS DOG 5-22 LBS (S60401AX), the product spilled on the owner. He is asymptomatic and washed his hands. No further medical information expected. Product quality: On 3 Apr 2019 the pet owner reported the following issue with an 8 pack of FRONTLINE PLUS DOG 5-22 LBS (S60401AX). The owner cut the blister packaging of 1 vial to get the vial out of the packaging. Once the blister packaging was open the vial was already open and spilled all over the owners hand. Owner did not notice any damage to the vial or the blister packaging prior to opening the packaging. The remaining 7 vials and outer packaging appear to be intact and undamaged. Product return is not expected as the owner disposed of the defective vial. No further information expected. 02-MAY-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot# S60401AX, expiry . Case investigated by France - Toulouse. Gotrack complaint closed on 2019-05-02. Final complaint evaluation A quality complaint was received for FRONTLINE PLUS Dog S, batch S60401AX, on 05april2019 . The defect is : the cut line on the back of the blister packaging is misplaced, cut through the bottom of one of the vials.. This is the second complaint for this batch Root cause : The aluminum used is the one expected for this batch, the production standards have been respected. As a result of the different layout of pipettes in the format by 4 (head to tail) compared to 3 (pipettes in the same direction) the cutting line is located at the level of the pipette when it is head down. It is therefore necessary to return the blister at the time of opening of the blister, but that information had not been clearly specified on the blister.

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											CAPA : A new aluminum has been developed for the format by 4 USA, the
05-Apr-2019	UHAE; 19US017966; MI; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 57.00 Year(s) **Weight:** 97 Pounds	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure (Off label use))	05-Apr-2019	05-Apr-2019	0 Day(s)	H-D	Human Exposure: On 5 Apr 2019, the following human exposure was reported to Safety Call International (SCI) by the patient, a 57 year old, 97 pound, female of further unknown signalment. 5 Apr 2019: The patient was applying one pipette of FRONTLINE PLUS DOG 89-132 LBS (S60601AR) to her dog about 20 minutes prior to the report. As she was opening the product, a drop of it flew up towards her eye. The patient could not confirm if the product had actually gone into her eye, but she proactively rinsed her eye in the shower for several minutes while holding her eyelid open. Her eye was a little red and a little irritated. It was noted that the patient has penicillin, tetanus, and compazine allergies. No further information at this time. UPDATE 10 Apr 2019: Per the pet owner, the caller rinsed her eye as advised and the symptoms resolved within an hour or so. No further medical information expected.
07-Apr-2019	UHAE; 19US018283; -; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 66.00 Year(s) **Weight:** Unknown	1	0	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 (Human exposure (Off label use))	07-Apr-2019	N/A	N/A	H-E	Human Exposure:On 7 April 2019, the following inquiry was reported to Safety Call International (SCI) by a 66 year old, female pet owner who had an exposure with FRONTLINE PLUS CATS (S40502AX). 7 April 2019: The caller contacted SCI to report that 10 minutes prior to calling, she had gotten FRONTLINE PLUS CATS ON HER HANDS. She briefly washed her hands after this and remains asymptomatic at this time. No other information is available.
10-Apr-2019	UHAE; 19US018568; OH; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** 68.00 Year(s) **Weight:** 200 Pounds	1	0	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 (Human exposure (Off label use))	10-Apr-2019	10-Apr-2019	0 Day(s)	H-E	Human Exposure: On 10 Apr 2019, the following human exposure was reported to Safety Call International (SCI) by the patient, a 68 year old, 200 pound, male. 10 Apr 2019: The patient could not open the container of FRONTLINE PLUS DOG 89-132 LBS (L62602), so the vial was cut with a knife. It caused the product to leak on his hands. The patient washed his hands with soap and water for quite a while and remained asymptomatic. It was noted that the patient has a history of hypertension and HA. No further medical information expected. Product quality: On 10 Apr 2019, a pet owner reported the following issue with one vial out of an unknown sized box of FRONTLINE PLUS DOG 89-132 LBS (L62602). The packaging was hard to open. The owner had to cut the packaging open with a knife and cut into the vial. Product return is not expected as the availability of the sample is unknown. No further information. UPDATE 11 Apr 2019: An attempt was made to get additional details regarding the product defect. To date, the information remains unknown. No further information. UPDATE 11 Apr 2019: SCI called the patient back for follow up. A message was left requesting follow up. No further information. UPDATE 15 Apr 2019: SCI called the patient back for follow up. A

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											message was left requesting follow up. No further information. UPDATE 17 Apr 2019: SCI called the patient back for follow up. A message was left requesting follow up. No further medical information expected. 20-MAY-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot# L62602, expiry . Case investigated by France - Toulouse. Gotrack complaint closed on 2019-05-20. Final complaint evaluation A product quality complaint for Frontline Plus Dog XL, batch L62602, was received by BIAH QA on 15april2019 The defect is : blister difficult to open This is the first complaint for this batch 4 complaints have been received for this kind of defect since january 2018 (all batches/formats of
10-Apr-2019	UHAE; 19US018628; NC; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 70.00 Year(s) **Weight:** 148 Pounds	1	0	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 (Human exposure (Off label use))	10-Apr-2019	10-Apr-2019	N/A	H-E	Product Quality: On 8 Apr 2019, the pet owner reported the following issue with a 6 pack of FRONTLINE PLUS CATS (R41206AW) (FL). One vial out of the package leaked into the blister cavity. The pet owner noticed the defect as she was opening the package, but cannot tell where the leak originated. There was no reported damage to the box. The remaining vials appear to be undamaged. Product return not expected as pet owner is unable to return the defective vial. No further information. Human Exposure: On 10 April 2019, the following inquiry was reported to Safety Call International (SCI) by a pet owner regarding a 148 pound, 70 year old female that was exposed to FRONTLINE PLUS CAT (R41206AW). 10 April 2019: The caller stated that she got some of the FRONTLINE PLUS CAT on her hands while taking it out of the packet. The caller immediately washed her hands with soap and water for a few minutes then washed her hands again for a few more minutes. The caller remains asymptomatic at this time. No other information is available. 17-MAY-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot# R41206AW, expiry . Case investigated by France - Toulouse. Gotrack complaint closed on 2019-05-17. Final complaint evaluation A product quality complaint for Frontline Plus Cat, batch R41206AW, was received by BIAH QA on 11april2019. The defect is : leaking pipette Cross-check for Recurrence : This is the 9th complaint for this defect regarding this batch Batch record review : This defect is well known, it represents 1 ppm of every batch produced in 2017. This defect is isolated to a few batches. The trend of this kind of defect is tracked monthly on Toulouse site (KPI). Should a batch have more than 20 complaints, whatever the defect , the batch record will be reviewed. Consequently, the batch record was not reviewed as per the internal TLS-SOP-000158. Complaint sample exam : not received/not requested Retention sample exam : Not
10-Apr-2019	UHAE; 19US018854; NJ; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** 51.00 Year(s)	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE	10-Apr-2019	10-Apr-2019	0 Day(s)	H-E	Product quality: On 10 Apr 2019 the pet owner reported the following information for an unknown size package of FRONTLINE PLUS DOG 5-22 LBS (Product unsubstantiated) (unknown lot). Owner has had difficulty opening the blister packaging for 20 years

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		Weight: Unknown				9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure (Off label use))					and while using scissor and a knife to open the blister packaging the owner cut into 1 vial. The vial spilled all over his hand. There was no damage to the blister packaging prior to the owner attempting to get 1 vial out. No picture or product is expected to be returned as the owner declined the report. Product and lot unknown because the owner refused to provide additional information. No further information expected. Human Exposure: On 10 April 2019, the following inquiry was reported to Safety Call International (SCI) by a pet owner regarding a 51 year old male that was exposed to FRONTLINE PLUS DOG 5-22 LBS (lot unknown). 10 April 2019: The caller stated that he got some of the FRONTLINE PLUS DOG 5-22 LBS on his hands while taking it out of the package. It was reported that the top of the vial came off after taking it out of the package, which resulted in the exposure. The caller immediately washed his hands with Dawn dish soap and water. The caller remains asymptomatic at this time. No other information is available. 20-MAY-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot# UNKNOWN, expiry . Case investigated by France - Toulouse. Gotrack complaint closed on 2019-05-20. Final complaint evaluation A TPC for Frontline Plus Dog S, batch unknown, was received on 15april2019. The defect is : blister difficult to open. 4 similar cases were received (including all batches of Frontline regular or combo for cats and dogs) since january 2018 Batch record review : This defect is very rare, it represents less than 0.03 ppm of every batch produced in 2017. In 2018, 4 cases were received (including all batches of Frontline regular or combo for cats and dogs) This defect is
11-Apr-2019	UHAE; 19US018967; TX; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 57.00 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?:** No (Human exposure (Off label use))	10-Apr-2019	11-Apr-2019	1 Day(s)	H-D	Product quality: On 11 Apr 2019 the pet owner reported the following information for an 8 pack of FRONTLINE PLUS DOG 23-44 LBS (S61602AX). The owner was using the product for the first time and cut along the dotted cut here line and into the bottom of 1 vial. The pet owner spilled the product all over her hand and got none on the dog. The owner opened a second vial and while holding the foil towards her and popping the top of the vial a drop of the product flew accross the room. The remaining 7 vials were intact and undamaged. There was no damage to the blister packaging or outer packaging of the product. No product or picture is expected to be returned as the owner disposed of the defective vial. No further information expected. Human Exposure: On 11 April 2019, the following event was reported to Safety Call International (SCI) by a pet owner regarding a 57 year old female that was exposed to FRONTLINE PLUS DOG 23-44 LBS (S61602AX). 10 April 2019: The caller was exposed to FRONTLINE PLUS DOG 23-44 LBS when she tried to open the product and some of it got on her hands. The caller immediately washed her hands with soap and water. 11 April 2019: The caller reported that she woke up earlier than normal with a sore throat and had flu-like symptoms. At the time of the call to SCI on 11 April 2019, these symptoms had returned to normal other than she was not in a good mood.

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											No other information is available. UPDATE 12 Apr 2019: Per the patient, she has remained asymptomatic since exposure. No further medical information expected.
11-Apr-2019	UHAE; 19US019029; -; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** 60.00 Year(s) **Weight:** 190 Pounds	1	0	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 (Human exposure (Off label use))	10-Apr-2019*	10-Apr-2019	N/A	H-E	Human Exposure: On 11 Apr 2019, the following human exposure was reported to Safety Call International (SCI) by the pet owner for himself, a 60 year old, 190 pound male. 10 Apr 2019: The owner's cat moved while applying FRONTLINE PLUS CATS (S40117AW) and some got on the owner's hands. He washed his hands and has remained asymptomatic. No further medical information expected.
11-Apr-2019	UHAE; 19US019188; NJ; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 58.00 Year(s) **Weight:** 195 Pounds	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure (Off label use))	11-Apr-2019	11-Apr-2019	0 Day(s)	H-D	Human Exposure: On 11 April 2019, the following event was reported to Safety Call International (SCI) by a pet owner regarding a 195 pound, 58 year old female that was exposed to FRONTLINE PLUS DOG 23-44 LBS (B43908BL) 11 April 2019: The caller stated that 10 minutes prior to calling SCI, when she opened the vial of FRONTLINE PLUS DOG 23-44 LBS a small amount of the product splashed into her left eye. She reported that the eye immediately started to burn, so she went to the sink to flush her eye with water for approximately 4 minutes. At the time of reporting, her eye had stopped burning, but felt stiff and dry. No other information is available. UPDATE: 12 April 2019: SCI called back the pet owner to obtain follow up information, but left a message because there was no answer. No other information is available. UPDATE: 15 April 2019: SCI called back the pet owner to obtain follow up information, but left a message because there was no answer. No other information is available. UPDATE: 17 April 2019: SCI called back the pet owner to obtain follow up information, but left a message because there was no answer. No other information is available.
17-Apr-2019	UHAE; 19US019841; IL; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 62.00 Year(s) **Weight:** Unknown	1	0	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 (Human exposure (Off label use))	15-Apr-2019*	15-Apr-2019	N/A	H-E	Human Exposure: On 15 Apr 2019, the following human exposure was reported to Safety Call International (SCI) by the pet owner for themselves, a 62 year old, female human of further unknown signalment. 15 Apr 2019: The pet owner applied the FRONTLINE PLUS DOG 5-22 LBS (R660308AL) to her dog of further unknown signalment. The pet owner was carrying her dog downstairs and kissed her dog in an unknown area about 4 hours and 40 minutes after applying the FRONTLINE. The pet owner then noticed the strong odor of the FRONTLINE on herself, and immediately washed her lips and nose with soap and water. The pet owner then gargled with Listerine. The pet owner is asymptomatic. No further medical information expected.

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16-Apr-2019	UHAE; 19US020400; GA; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 30.00 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?:** No (Human exposure (Off label use))	16-Apr-2019	16-Apr-2019	0 Day(s)	H-D	Human Exposure: On 16 Apr 2019, the following human exposure was reported to Safety Call International (SCI) by the patient, a 30 year old female of further unknown signalment. 16 Apr 2019: The patient applied FRONTLINE PLUS DOG 23-44 LBS (R61020AL) to her dog, but accidently got the product on her hand. She washed her hands thoroughly a few minutes after exposure. After an unknown period of time, she developed a slight tingling sensation on the skin of her hand. It was noted that the patient has a history of anxiety. No further medical information expected. UPDATE 23 April 2019: SCI attempted to call back the patient, but was unable to reach her. A message was left requesting follow up. No other information is available. UPDATE 25 April 2019: SCI called the patient and the patient rinsed the area as advised; symptoms resolved later that evening. No other information is available.
17-Apr-2019	UHAE; 19US020515; CA; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 36.00 Year(s) **Weight:** 210.000 Pounds	1	0	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 (Human exposure (Off label use))	17-Apr-2019*	17-Apr-2019	N/A	H-E	Human Exposure: On 17 Apr 2019, the following human exposure was reported to Safety Call International (SCI) by the pet owner for themselves, a 36 year old, 210 pound, female human of further unknown signalment. 17 Apr 2019: The pet owner applied the FRONTLINE PLUS DOG 5-22 LBS (lot number unknown) to a dog of further unknown signalment, and accidentally got an unknown amount on her hands. The pet owner immediately washed her hands and is asymptomatic. No further medical information expected.
17-Apr-2019	UHAE; 19US020658; NJ; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** 75.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure (Off label use))	17-Apr-2019	17-Apr-2019	N/A	H-E	Human Exposure: On 17 Apr 2019, the following human exposure was reported to Safety Call International (SCI) by the patient, a 75 year old, non-pregnant female of further unknown signalment. 17 Apr 2019: A splash of FRONTLINE PLUS CATS (R0179) (invalid lot) got into the patient's eye. She rinsed her eye with water for 2-10 seconds. She was asymptomatic and remained asymptomatic at least 5-10 minutes later. It was noted that she does not wear contact lenses, she has unknown medication allergies, and she has a history of hypertension. No further medical information expected.
17-Apr-2019	UHAE; 19US020800; -; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 36.00 Year(s) **Weight:** 210 Pounds	-	-	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	17-Apr-2019	N/A	N/A	H-E	Product quality:As reported by a pet owner to Safety Call International (SCI), the space where the lot number is supposed to be located on the box of FRONTLINE PLUS DOG 5-22 LBS (UNKNOWN) was blank. Product return and a photograph of the defect is not expected as the caller declined giving out her phone number so she cannot be contacted. No other information is available. Human Exposure: On 17 April 2019, the following inquiry was reported to Safety Call International (SCI) by a 210.0 pound, 36 year old, female pet owner who had an exposure with FRONTLINE

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						Was the product used ok?: No (Human exposure (Off label use))					PLUS DOG 5-22 LBS (UNKNOWN). 17 April 2019: Caller states 30-45 minutes prior to calling SCI, she was applying this product on her dog and some it accidentally got on her hands. The caller immediately washed her hands and remains asymptomatic at this time. No other information is available. 31-MAY-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot# UNKNOWN, expiry . Case investigated by France - Toulouse. Gotrack complaint closed on 2019-05-31. Final complaint evaluation A product quality complaint for FRONTLINE PLUS DOG, lot number unknown, was received by BIAH QA on the 30 April 2019. The complaint description is : box missing lot number This is the twenty-sixth complaint received for this defect, in the past 12 months, all batches included (Frontline plus Dog) Batch record review: batch unknown Root cause: Jam on packaging line Description: This defect can be caused by jams that occurred on the packaging line at the level of the cartooning machine, just after the ink jet. Therefore, an accumulation of carton boxes after the ink-jet can also block the carton boxes that are placed just before the ink jet. However, since this part of the cartooning machine continues running, the carton boxes continue to be deposited by the mechanical arm (placed before the ink-jet). Therefore, when the carton boxes pass in front of the ink jet, they are very close to
18-Apr-2019	UHAE; 19US020893; CA; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 70.00 Year(s) **Weight:** 120 Pounds	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 (Human exposure (Off label use))	08-Apr-2019*	10-Apr-2019	2 Day(s)	H-D	Human Exposure: On 18 Apr 2019, the following human exposure was reported by the pet owner to Safety Call International (SCI) for herself, a 120 lb, 70 year old female. 8 Apr 2019: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades by the DVM to the owner's cat. 10 Apr 2019: After carrying the cat around, the owner developed numbing of the lips, the taste of the product in her mouth, dizziness and blurry vision. She has been treating with eye drops and drinking fluids. Her signs are currently ongoing. The owner's cat also experienced a reaction 19US020617. No further medical information is expected. UPDATE 22 Apr 2019: Per the patient, she has been limiting contact with her cat and her symptoms resolved on an unknown date. The patient will be visiting a doctor on 24 Apr 2019. No further medical information is expected.
19-Apr-2019	UHAE; 19US020916; MI; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	19-Apr-2019*	N/A	N/A	H-E	Human Exposure: On 19 Apr 2019, the following human exposure inquiry was reported to Safety Call International (SCI) by the pet owner for themselves, a male human of further unknown signalment. 19 Apr 2019: The pet owner attempted to apply FRONTLINE PLUS DOG 45-88 LBS (S60403AX) to a dog of further unknown signalment, and was exposed to an unknown amount of FRONTLINE PLUS on his hands. The pet owner is asymptomatic. No further medical information is 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
						product used ok?: No (Human exposure (Off label use))					
22-Apr-2019	UHAE; 19US021454; PA; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 60.00 Year(s) **Weight:** 170.000 Pounds	1	1	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 (Human exposure (Off label use))	22-Apr-2019*	22-Apr-2019	0 Day(s)	H-D	Human Exposure: On 22 Apr 2019, the following human exposure was reported to Safety Call International (SCI) by the pet owner for herself, a 170 lb, 60 year old female. 22 Apr 2019: The pet owner applied FRONTLINE PLUS DOG 23-44 LBS (R61020AL) to her 2 dogs and wore gloves, but removed 1 glove to open the product, so it came into contact with her finger. She immediately washed her hands. About an hour and a half later, she began experiencing upper abdominal pain and burping, and has eaten less than normal and drank water, and taken a Tums for treatment. She does have a history of seasonal allergies. No further medical information expected. UPDATE 23 Apr 2019: Per SCI call to reporter, she feels her symptoms are likely due to a stomach virus as her son had gastrointestinal upset the day prior and her symptoms were the same as his. No further medical information expected.
24-Apr-2019	UHAE; 19US021985; -; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 42.00 Year(s) **Weight:** 185 Pounds	1	1	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 (Human exposure (Off label use))	24-Apr-2019	24-Apr-2019	0 Day(s)	H-D	Product quality: On 24 Apr 2019, the pet owner reported the following issue with a 3 pack of FRONTLINE PLUS DOG 45-88 LBS (R62001AR). When the owner went to open the 2 vials of the product they were leaking inside the foil packaging. No evidence of tampering. The other 1 vial was undamaged. Product return expected, 1 defective vial. No further information. Human Exposure:On 24 April 2019, the following event was reported to Safety Call International (SCI) by a 42 year old, 185 pound, pet owner with exposure to FRONTLINE PLUS DOG 45-88 LBS (R62001AR). 24 April 2019: The caller stated that when opening the package, she found that the product was leaking. It is unknown if the product leaked on her skin, but she had immediately experienced a bitter taste. Once she realized the product was leaking, she rinsed her mouth with water and is now asymptomatic. Her husband was also exposed (19US022310) and he is asymptomatic. No other information is available. 24-May-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot # R62001AR, expiry UNKNOWN. Case investigated by France - Toulouse. Gotrack complaint closed on 2019-05-24. A product quality complaint for Frontline Plus Dog L , batch R62001AR, was received by BIAH QA on 25april2019. The defect is : leaking pipette Cross-check for Recurrence: This is the 2nd complaint for this defect regarding this batch Batch record review: This defect is well known, it represents 1 ppm of every batch produced in 2017. This defect is isolated to a few batches. The trend of this kind of defect is tracked monthly on Toulouse site (KPI). Should a batch have more than 20 complaints, whatever the defect , the batch record will be reviewed. Consequently, the batch record was not reviewed as per the internal TLS-SOP-000158.

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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
											Complaint sample exam : not received/not requested Retention sample exam : Not reviewed : the retention sample is stored for identification purposes. Therefore, it
24-Apr-2019	UHAE; 19US022014; MA; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 9.00 Year(s) **Weight:** 70 Pounds	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** - **Was the product used ok?:** No (Human exposure (Off label use))	24-Apr-2019	24-Apr-2019	N/A	H-E	Human Exposure: 24-APR-2019 Per SCI report: Caller recently applied product to dog and 10 minutes ago daughter went up and kissed the dog at the application site. Daughter is asymptomatic but caller would like to know of any poisoning concerns. No event reported.
24-Apr-2019	UHAE; 19US022310; NY; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** 43.00 Year(s) **Weight:** 180.000 Pounds	-	-	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 (Human exposure (Off label use))	24-Apr-2019	N/A	N/A	H-E	Human Exposure:On 24 April 2019, the following event was reported to Safety Call International (SCI) by a 42 year old, 185 pound, male pet owner with exposure to FRONTLINE PLUS DOG 45-88 LBS (R62001AR). 24 April 2019: The caller stated that when was applying the product her pet, the top popped off and flew into her husbands hands. He rinsed with water within 1 minute and is asymptomatic. The caller, herself, had immediately experienced a bitter taste after the product started leaking (19US021985). No other information is available.
29-Apr-2019	UHAE; 19US022823; TX; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** 77.00 Year(s) **Weight:** 165.000 Pounds	1	1	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 (Human exposure (Off label use))	29-Apr-2019	29-Apr-2019	0 Day(s)	H-E	Human Exposure: On 29 Apr 2019, the following human exposure was reported to Safety Call International (SCI) by the patient, a 77 year old, 165 pound, non-pregnant female. 29 Apr 2019: The patient got some FRONTLINE PLUS DOG 23-44 LBS (S61602AX) on her right hand as she took the vial out of the wrapper. The vial was torn. The owner rinsed her hands for approximate 20 seconds and remained asymptomatic. It was noted that the patient has a history of hypertension, high cholesterol, hyperthyroidism, and back pain. No further medical information expected. Product quality: On 29 Apr 2019, a patient reported the following issue with FRONTLINE PLUS DOG 23-44 LBS (S61602AX). One vial out of an unknown sized package was torn. It is unknown where on the vial the tear was located. It is unknown if the packaging was damaged. Product return is not expected as it was not requested due to the leaking product not being contained. Pictures are not expected as it is unknown if the sample is still available. No further information. 29-MAY-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot# S61602AX, expiry . Case investigated by France - Toulouse. Gotrack complaint closed on 2019-05-29. Final complaint evaluation A product quality complaint for 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
											Plus Dog M, batch S61602AX, was received by BIAH QA on 30april2019. The defect is : leaking pipette Cross-check for Recurrence : This is the 1st complaint for this defect regarding this batch Batch record review : Leaking defect is well known, it represents 1 ppm of every batch produced in 2017. This defect is isolated to a few batches. The trend of this kind of defect is tracked monthly on Toulouse site (KPI). Should a batch have more than 20 complaints, whatever the defect , the batch record will be reviewed. Consequently, the batch record was not reviewed as per the internal TLS-SOP-000158. Complaint sample exam : not received/not requested . No specific investigation about
01-May-2019	UHAE; 19US023438; MA; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 34.00 Year(s) **Weight:** 133 Pounds	-	-	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 (Human exposure (Off label use))	01-May-2019	N/A	N/A	H-E	Human Exposure: On 1 May 2019, the following inquiry was reported to Safety Call International (SCI) by a 34-year-old, 133-pound, 8 months pregnant (unknown if lactating) pet owner who had an exposure with FRONTLINE PLUS DOG 45-88 LBS (unknown). 1 May 2019: Caller touched the area on her dog where she had applied FRONTLINE PLUS DOG 45-88 LBS. This exposure occurred 20 minutes prior to contacting SCI. The caller washed her hands and face with dish soap and remains asymptomatic. No other information is available. UPDATE 13 May 2019: SCI attempted to call back the patient on 7 May 2019, 9 May 2019, and 13 May 2019 and left messages requesting follow up. No other information is available.
01-May-2019	UHAE; 19US023526; -; U.S.A	**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 (Human exposure (Off label use))	01-May-2019	01-May-2019	N/A	H-E	Human Exposure: On 1 May 2019, the following human exposure was reported by the pet owner for herself, a female of unknown signalment. 1 May 2019: The pet owner was using FRONTLINE PLUS DOG 45-88 LBS (Lot Unknown) for the first time for her dog, and some of the product got on her hand. She washed her hand and is asymptomatic. No further medical information expected.
29-Apr-2019	UHAE; 19US023645; -; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 70.00 Year(s) **Weight:** 177.000 Pounds	-	-	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	29-Apr-2019	N/A	N/A	H-E	Human Exposure:On 29 April 2019, the following inquiry was reported to Safety Call International (SCI) by a 70-year-old, 177-pound pet owner who had an exposure with FRONTLINE PLUS CAT (M40205AW) 29 April 2019: Caller stated that she was applying FRONTLINE PLUS CAT (M40205AW) to her cat and some of the product got on her hands. She immediately washed her hands with soap and water 3 times. She is currently asymptomatic. No other information is available.

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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
						ok?: No (Human exposure (Off label use))					
02-May-2019	UHAE; 19US023989; TX; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** 68.00 Year(s) **Weight:** 235.000 Pounds	1	1	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 (Human exposure (Off label use))	02-Apr-2019*	02-May-2019	0 Day(s)	H-E	Product quality: On 2 May 2019, the pet owner reported the following issue with a 8 pack of FRONTLINE PLUS DOG 45-88 LBS (lot unknown). When the owner cut along the dotted line of the card he cut into the well of 2 vials of the product. The product was spilled all over the pet owner's counter and hands. The other 6 vials were undamaged. Product return not expected because owner refused. No further information. UPDATE 3 May 2019: After internal review, it was noted that the lot number for the FRONTLINE PLUS DOG 45-88 LBS is S61202. No further information. Human Exposure: On 2 May 2019, the following was reported to Safety Call International (SCI) by the patient, a 68 year old, 235 pound, male. 2 Apr 2019*: The patient cut the packaging of FRONTLINE PLUS DOG 45-88 LBS (S61202) along the dotted line according to labeled instructions. The patient got the product on both of his hands. He washed his hand with dish soap and water and was asymptomatic 2 May 2019: The patient cut the packaging of FRONTLINE PLUS DOG 45-88 LBS along the dotted line according to labeled instructions. The patient got the product on his right hand. He washed his hand with dish soap and water and was asymptomatic. It was noted that the patient has a history of high blood pressure. No further medical information expected. 29-MAY-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot# S61202, expiry . Case investigated by France - Toulouse. Gotrack complaint closed on 2019-05-29. Final complaint evaluation A TPC was received for FRONTLINE PLUS dog, batch S61202AX, on 03may2019 . The defect is : the cut line on the back of the blister packaging is misplaced, leading to cut through the bottom of one of the vials. This is the 1st complaint for this batch Batch record review and retention sample : not reviewed as the aluminum used is the one expected for this batch, the production standards have been respected Root cause : The aluminum used is
16-May-2019	UHAE; 19US027166; KY; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 64.00 Year(s) **Weight:** 130.000 Pounds	-	-	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 (Human exposure (Off label use))	16-May-2019	N/A	N/A	H-E	Human Exposure: On 16 May 2019, the following inquiry was reported to Safety Call International (SCI) by a >64-year-old, 130-pound, female pet owner who had an exposure with FRONTLINE PLUS CATS (S40101BW). 16 May 2019: Approximately 10 minutes prior to contacting SCI, the pet owner was opening the foil backing of the FRONTLINE PLUS CATS and in doing so ripped the vial itself. The pet owner got some of the product on her fingers. She immediately washed her hands under cool water without using soap; she remains asymptomatic at this time. No other medical information is available. UPDATE 23 May 2019: SCI attempted to call the pet owner back three times, on 21 May 2019, 23 May 2019, and May 28 2019 and left a message each time. No other information is available.

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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
16-May-2019	UHAE; 19US027368; MA; U.S.A	**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 (Human exposure (Off label use))	16-May-2019*	16-May-2019*	N/A	H-E	Human Exposure: On 16 May 2019, the following human exposure was reported by the pet owner for herself, a female of unknown signalment. Unknown date: The pet owner got some FRONTLINE PLUS DOG 23-44 LBS (Lot Unknown) on her hands and washed immediately. She is asymptomatic. No further medical information expected.
21-May-2019	UHAE; 19US028271; UT; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 69.00 Year(s) **Weight:** 140 Pounds	1	1	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 (Human exposure (Off label use))	21-May-2019	21-May-2019	0 Day(s)	H-D	Human Exposure: On 21 May 2019, the following human exposure was reported by the pet owner to Safety Call International (SCI) for herself, a 140 lb, 69 year old female. 21 May 2019: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (M62914AL) topically to her dog. The dog jumped up and smeared the wet product on her hand. She washed with soap and water for 10 minutes, and now is getting a headache. The pet owner has a history of allergies to Zofran and nickel. No further medical information expected. 22 May 2019: SCI follow up noted symptoms resolved a few minutes later with no additional treatments, caller remains asymptomatic. No further medical information expected.
23-May-2019	UHAE; 19US028758; NJ; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 60.00 Year(s) **Weight:** 128 Pounds	1	0	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 (Human exposure (Off label use))	23-May-2019	23-May-2019	N/A	H-E	Human Exposure: On 23 May 2019, the following human exposure was reported by the pet owner to Safety Call International (SCI) for herself, a 60 year old, 128 lb female. 23 May 2019: The pet owner used a knife to open the package of FRONTLINE PLUS DOG 23-44 LBS (P61322) and product got all over her hands. She washed her hands several times and is asymptomatic. No further medical information expected.
23-May-2019	UHAE; 19US028925; WA; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	23-May-2019	23-May-2019	0 Day(s)	H-E	Human Exposure: On 23 May 2019, the following human exposure was reported by the pet owner for herself, other signalment unknown. 23 May 2019: When the owner cut through the packaging on FRONTLINE PLUS CATS (S40301AX), the product spilled and leaked onto the owner's hands. She is asymptomatic. No further medical information expected. Product quality: On 23 May 2019 the owner reported the following issue with an 8 pack of FRONTLINE PLUS CATS (S40301AX). When the owner cut along the dotted line to remove 2 vials the vials spilled and leaked all over the owners hands. The owner

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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?: No (Human exposure (Off label use))					inadvertently cut through the bottom of 1 vial and the tip of the other vial causing the liquid to pour out of both vials. The remaining 6 vials are not damaged. The blister packaging and outer packaging were intact and undamaged. No product or picture is expected to be returned as the owner disposed of both vials. No further information expected. 19-JUN-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot# S40301AX, expiry . Case investigated by France - Toulouse. Gotrack complaint closed on 2019-06-19. Final complaint evaluation A TPC was received for FRONTLINE PLUS cat, batch S40301AX, on 25may2019 . The defect is : the cut line on the back of the blister packaging is misplaced, leading to cut through the bottom of one of the vials. This is the 5th complaint for this batch Batch record review and retention sample : not reviewed as the aluminum used is the one expected for this batch, the production standards have been respected Root cause : The aluminum used is the one expected for this batch, the production standards have been respected. As a result of the different layout of pipettes in the format by 4 (head to tail) compared to 3 (pipettes in the same direction) the cutting line is located at the level of the pipette when it is head down. It is therefore necessary to return the blister at the time of opening of the
24-May-2019	UHAE; 19US029473; NJ; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 50.00 Year(s) **Weight:** Unknown	1	0	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 (Human exposure (Off label use))	24-May-2019	24-May-2019	N/A	H-E	Human Exposure: On 24 May 2019, the following human exposure was reported by the pet owner to Safety Call International (SCI) for herself, a 50 year old female, other signalment unknown. 24 May 2019: The pet owner was applying FRONTLINE PLUS DOG 45-88 LBS (PP23381) tp her dog when the product got on her hands. She washed her hands for 10 minutes and is asymptomatic. No further medical information expected.
26-May-2019	UHAE; 19US029509; CA; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 77.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical and Oral **Was the product used**	26-May-2019	26-May-2019	0 Day(s)	H-D	Human Exposure: 26 MAY 2019 Human patient reported the following event to Safety Call International. 26 MAY 2019 Animal owner applied *FRONTLINE PLUS 0-22 (no serial available) to her pet this afternoon. Later in the day she kissed the back of the pet's neck. She did experience a numbness to the tongue that is subsiding. Caller stated she rinsed her mouth out and brushed her teeth. 31 MAY 2019 Human patient reported symptoms resolved without intervention. No further medical information expected. UPDATE 15 JUL 2019: completed expectedness box.

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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
						ok?: No (Human exposure (Off label use))					
28-May-2019	UHAE; 19US029539; TX; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** 72.00 Year(s) **Weight:** 185.000 Pounds	1	1	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 (Human exposure (Off label use))	28-May-2019	28-May-2019	N/A	H-E	Human Exposure: On 28 May 2019, the following human exposure was reported by the pet owner to Safety Call International (SCI) for her husband, a 72 year old, 185 lb male. 28 May 2019: The husband applied FRONTLINE PLUS DOG 45-88 LBS (H64106AR) to his dog, and accidently got product on his finger. He washed with soap and water twice and is asymptomatic. No further medical information expected.
29-May-2019	UHAE; 19US029768; VA; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** 78.00 Year(s) **Weight:** 163 Pounds	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 (Human exposure (Off label use))	29-Mar-2019	05-Apr-2019*	1 Week(s)	H-D	Human Exposure: On 29 May 2019, the following human exposure was reported by the pet owner to Safety Call International (SCI) for himself, a 163 lb, 78 year old male. 29 Mar 2019: The pet owner applied FRONTLINE PLUS CATS (H40304) to his cat. 5 Apr 2019*: The owner broke out in a red itchy rash around his waist/back and around the left inside of his arm. He believes the product got on his skin while he was sitting next to his cat. 9 Apr 2019: He went to the dermatologist who prescribed prednisone, which did not help. 17 Apr 2019: He returned to the dermatologist, where he was given 5 mg of prednisone TID until the next visit, and triamcinolone 1% BID for 1 week as the rash had moved around his body to where he places his underwear. 8 May 2019: He was placed on more prednisone 5 mg TID, triamcinolone ointment and several sample creams. The dermatologist noted that he was somewhat sensitive to parabens. The reporter's symptoms are improving. He has a history of testicular cancer in the 1980's, a heart stint, high cholesterol, seasonal allergies, hypertension and a heart stint. No further medical information expected. UPDATE: 12 Jun 2019: SCI followed up with patient and it was noted he is doing much better and the itching has stopped.
29-May-2019	UHAE; 19US029778; NJ; U.S.A	**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?:** No (Human exposure (Off label use))	22-May-2019*	22-May-2019*	N/A	H-E	Human Exposure: On 29 May 2019, the following human exposure was reported by the pet owner for himself, signalment unknown. 22 May 2019:*: When the packaging of FRONTLINE PLUS DOG 45-88 LBS (S61603AX) was opened, the product was leaking and got onto the owner. He washed his hands and is asymptomatic, and declined being transferred to poison control. No further medical information expected. Product quality: On 29 May 2019, the pet owner reported the following issue with FRONTLINE PLUS DOG 45-88 LBS (S61603AX). One vial from the eight pack was leaking inside the sealed foil blister cavity. There was no obvious damage to the box or blister cavity and the other seven vials were intact. The reporter couldn't verify, but thought it was possible that the neck of the reported vial may have been bent. He didn't notice the leaking or possible damage until after he opened the respective blister cavity

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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
											and the product got onto him. Neither a photograph nor product return is expected as it was already discarded. No further information. 19-JUN-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot# S61603AX, expiry . Case investigated by France - Toulouse. Gotrack complaint closed on 2019-06-19. Final complaint evaluation A product quality complaint for Frontline Plus Dog L, batch S61603AX, was received by BIAH QA on 30may2019. The defect is : leaking pipette Cross-check for Recurrence : This is the 1st complaint for this defect regarding this batch Batch record review : This defect is well known, it represents 1 ppm of every batch produced in 2017. This defect is isolated to a few batches. The trend of this kind of defect is tracked monthly on Toulouse site (KPI). Should a batch have more than 20 complaints, whatever the defect , the batch record will be reviewed. Consequently, the batch record was not reviewed as per the internal TLS-SOP-000158. Complaint sample exam : not received/not requested Retention sample exam :
27-May-2019	UHAE; 19US029849; NH; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 46.00 Year(s) **Weight:** Unknown	1	0	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 (Human exposure (Off label use))	27-May-2019*	27-May-2019	N/A	H-E	Human Exposure: On 27 May 2019, the following human exposure inquiry was reported to Safety Call International (SCI) by the pet owner for themselves, a 46 year old, female human of further unknown signalment. 27 May 2019: The pet owner applied FRONTLINE PLUS DOG 23-44 LBS (S61006AL) to her dog of unknown signalment. The pet owner was exposed to an unknown amount of FRONTLINE PLUS on her hands while combing through her dog's hair coat. The pet owner immediately washed her hands with soap and water, and then applied hand cream. The pet owner was asymptomatic. No further medical information expected.
31-May-2019	UHAE; 19US030725; OK; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** 66.00 Year(s) **Weight:** 140.000 Pounds	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 (Human exposure (Off label use))	23-May-2019	26-May-2019	3 Day(s)	H-D	Human Exposure: On 31 May 2019, the following human exposure was reported to Safety Call International (SCI) by the family member for a patient, a 66 year old, 140 pound, non-pregnant female. 23 May 2019: The patient accidently got FRONTLINE PLUS CATS (S41404AW) on her finger while using the product on her cats. The patient washed her finger. 26 May 2019: The patient developed nausea and weakness. Unknown dates: The patient presented to a doctor twice where unknown tests were performed to rule out potential causes. Bloodwork was performed which eliminated the suspicion of pancreatitis. A CT scan was performed to rule out gallstones. She was given ABT. At the time of the report, the symptoms were ongoing. No further information at this time. UPDATE 3 Jun 2019: Per the family member, the patient is still experiencing symptoms and will undergo further testing this week. No further information at this time. UPDATE 10 JUN 2019: Per family member the patient had an endoscopy performed, and Medical doctor diagnosed her as

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											having gastritis. The cause is unknown, but her symptoms are much improved. Caller did not wish to talk further. No further medical information expected.
05-Jun-2019	UHAE; 19US031599; OH; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 59.00 Year(s) **Weight:** 160 Pounds	-	-	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 (Human exposure (Off label use))	05-Jun-2019	N/A	N/A	H-E	Human Exposure: On 5 June 2019, the following inquiry was reported to Safety Call International (SCI) by a 59 year old, 160 pound pet owner who had an exposure with FRONTLINE PLUS CATS (R41118AW). 5 June 2019: Fifteen minutes prior to calling SCI, the pet owner petted her cat that had just received FRONTLINE PLUS CATS on this day. She washed her hands immediately and it not fully certain that he touched the product when she petted her cat. She remains asymptomatic at this time. No other information is available.
05-Jun-2019	UHAE; 19US031935; OH; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** - **Weight:** Unknown	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure (Off label use))	05-Jun-2019	05-Jun-2019	N/A	H-E	Human Exposure: On 5 Jun 2019, the following human exposure was reported to Safety Call International (SCI) by the patient, a non-pregnant female of further unknown signalment. 5 Jun 2019: As the patient was opening FRONTLINE PLUS CATS (lot number unknown), the product contents splashed in her left eye. The patient washed her eye with water and was asymptomatic. It was noted that the patient does not wear contact lenses. The patient was not forthcoming with information and declined providing her complete prior medical history and lot number. No further information at this time. UPDATE 17 Jun 2019: Multiple attempts made by SCI to acquire follow up details, no response. No further medical information expected.
06-Jun-2019	UHAE; 19US032056; -; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** 63.00 Year(s) **Weight:** 135 Pounds	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure (Off label use))	06-Jun-2019	06-Jun-2019	0 Day(s)	H-D	Human Exposure: 6 JUN 2019 Safety Call International (SCI) reported the following event. 6 JUN 2019 Caller stated his wife was applying FRONTLINE PLUS for DOGS (23-44lbs) (M63306AL) to their dog and some of the product got into both of the owner's eyes about 5-10 minutes prior to call. She does not wear contact lenses and she rinsed eye then used saline to rinse eyes. She is having irritation. UPDATE:12 JUN 2019 SCI attempted to obtain follow up details, no response. No further medical information expected.
06-Jun-2019	UHAE; 19US032109; NC; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 61.00 Year(s) **Weight:** 112 Pounds	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	06-Jun-2019	06-Jun-2019	0 Day(s)	H-D	Human Exposure: On 6 Jun 2019, the following event was reported by the pet owner to Safety Call International (SCI) for herself, a 61 year old, 112 lb female. 6 Jun 2019: The pet owner was applying FRONTLINE PLUS 5-22 LBS (S62502AW) to her dog when a little drop got on her finger. She washed her hands with dish soap and is experiencing anxiety. She has a history of hay fever, an allergy to bee stings, anxiety,

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						products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure (Off label use))					depression, fibromyalgia, irritable bowel syndrome and PTSD. UPDATE: 12 Jun 2019: SCI made multiple attempts to acquire follow up details, no response. No further medical information expected.
07-Jun-2019	UHAE; 19US032350; MD; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 57.00 Year(s) **Weight:** 220.000 Pounds	1	0	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 (Human exposure (Off label use))	05-Jun-2019*	N/A	N/A	H-E	Product quality: On 7 Jun 2019, the pet owner reported the following issue with a 3 pack of FRONTLINE PLUS DOG 5-22 LBS (S61006AL). When the owner went to use last vial of 3 pack it was leaking inside of blister pack. The blister cavity that contained the vial was present, sealed, undamaged, but was leaking. Product return not expected as owner threw away vial. No further information. Human Exposure: On 7 Jun 2019, the following human exposure was reported to Safety Call International (SCI) by the pet owner for themselves, a 57 year old, 220 pound, female human of further unknown signalment. 5 Jun 2019: The pet owner was exposed to an unknown amount of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) all over her hands as she pealed back the foil of the product. The pet owner was asymptomatic. No further medical information expected.
07-Jun-2019	UHAE; 19US032429; IL; U.S.A	**Sex:** M **Sex qualifier:** -**Age:** 3.00 Year(s) **Weight:** 45 Pounds	1	0	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 (Human exposure (Off label use))	07-Jun-2019*	07-Jun-2019	N/A	H-E	Human Exposure: On 7 Jun 2019, the following call was reported to Safety Call International (SCI) by the pet owner for a 3 year old, 45 lb male child. 7 Jun 2019: A dose of FRONTLINE PLUS DOG 45-88 LBS (Lot Unknown) was applied to a dog, and then the child put their mouth on the dog at the application site. The child is asymptomatic. UPDATE: 17 Jun 2019: Multiple attempts made by SCI for follow up, no response. No further medical information expected.
10-Jun-2019	UHAE; 19US032699; TX; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	0	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 (Human exposure (Off label use))	10-Jun-2019	N/A	N/A	H-E	Human Exposure: On 10 Jun 2019, the following event was reported by the pet owner for herself, a female of unknown signalment. 10 Jun 2019: The pet owner cut open the vial of FRONTLINE PLUS CATS (S40815BW) and the product spilled onto her hands. She is asymptomatic. No further medical information expected. Product quality: On 10 Jun 2019, the pet owner reported the following issue with FRONTLINE PLUS CATS (S40815BW). The pet owner cut the cut line on the vial and the product spilled out and was wasted on her hands before she could apply to the pet. The vial and blister appear undamaged . No product return is expected, owner declined. No further information is expected.
11-Jun-2019	UHAE; 19US033164;	**Sex:** F **Sex qualifier:**	1	0	0	**Product used:** FIPRONIL	11-Jun-2019	11-Jun-2019	N/A	H-E	Human Exposure: On 11 Jun 2019, the following event was reported by the pet owner for herself, a female of unknown

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	MI; U.S.A	Unknown**Age:** - **Weight:** Unknown				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure (Off label use))					signalment. 11 Jun 2019: The pet owner got an unknown amount of FRONTLINE PLUS DOG 45-88 LBS (R60206AR) on her left hand. She is asymptomatic. No further medical information expected.
12-Jun-2019	UHAE; 19US033779; VA; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** 23.00 Year(s) **Weight:** 133.000 Pounds	1	-	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure (Off label use))	12-Jun-2019	N/A	N/A	H-E	Human Exposure: 12-JUN-2019 Safety Call International (SCI) reported the following event. 12-JUN-2019 Caller contacted SCI noting his wife was opening the package (FRONTLINE PLUS FOR DOGS 45-88lbs) (T62501AR) and when it opened some got into her eye. She has rinsed and having no symptoms at this time. She does not wear contacts. No further medical information expected.
13-Jun-2019	UHAE; 19US033906; CA; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	0	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 (Human exposure (Off label use))	13-Jun-2019	N/A	N/A	H-E	Product quality: On 13 Jun 2019 the pet owner reported the following issue with an 8 pack of FRONTLINE PLUS DOG 45-88 LBS (S60502AX). The owner took the blister packaging out of the outer packaging and proceeded to cut 1 vial out of the blister packaging along the dotted cut here line. The owner cut through the bottom of the vial and the product spilled all over the owners hand. The remaining 7 vials are intact and undamaged. No product will be sent in as the owner disposed of the defective vial. No further information is expected. Human Exposure: On 13 Jun 2019, the following human exposure inquiry was reported to Safety Call International (SCI) by the pet owner for themselves, a male human of further unknown signalment. 13 Jun 2019: The pet owner was exposed to an unknown amount of FRONTLINE PLUS DOG 45-88 LBS (S60502AX) on his finger while attempting to open to open the package. The pet owner is asymptomatic. No further medical information expected.
15-Jun-2019	UHAE; 19US034672; CA; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** 77.00 Year(s) **Weight:** 180 Pounds	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous	15-Jun-2019	15-Jun-2019	N/A	H-E	Human Exposure: On 15 Jun 2019, the following human exposure was reported to Safety Call International (SCI) by the patient, a 77 year old, 180 pound, non-pregnant female. 15 Jun 2019: The patient got an unknown volume of FRONTLINE PLUS DOG 5-22 LBS (lot number unknown) on her thumb 15-20 minutes prior to contacting SCI. She rinsed the exposed area with soap and water and remained asymptomatic. It was noted that the patient has a history of hypertension and high cholesterol. No further information at this time.

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						Was the product used ok?: No (Human exposure (Off label use))					
17-Jun-2019	UHAE; 19US034676; MO; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	-	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 (Human exposure (Off label use))	15-Jun-2019	N/A	N/A	H-E	Human Exposure: On 17 Jun 2019, Safety Call International (SCI) reported the following event. 15 Jun 2019: Owner went to administer FRONTLINE PLUS DOG 23-44 LBS (S60402AX) to her dog. The owner complained that dotted line indicated that she cut across the bottom entirely. In doing so, she cut completely through the bottom of one vial from an 8 pack. She opened the package the way she was supposed to and it got on her hand. She washed it off right away. She is asymptomatic. Product nor photos are expected as they have been discarded. No further information expected. 16-JUL-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot# S60402AX, expiry . Case investigated by France - Toulouse. Final complaint evaluation A TPC was received for FRONTLINE PLUS dog, batch S60402AX, on 19june2019 . The defect is : the cut line on the back of the blister packaging is misplaced, leading to cut through the bottom of one of the vials. This is the 3rd complaint for this batch Batch record review and retention sample : not reviewed as the aluminum used is the one expected for this batch, the production standards have been respected Root cause : The aluminum used is the one expected for this batch, the production standards have been respected. As a result of the different layout of pipettes in the format by 4 (head to tail) compared to 3 (pipettes in the same direction) the cutting line is located at the level of the pipette when it is head down. It is therefore necessary to return the blister at the time of opening of the blister, but that information had not been clearly specified on the blister. CAPA : A new aluminum has been developed for the format by 4 USA, the cutting line is shifted and an explanatory scheme is printed on the back of the blister to specify how to open the blister. This new aluminum has been online since September 2018. Conclusion : The complaint is justified and assessed as major without
19-Jun-2019	UHAE; 19US035342; NY; U.S.A	**Sex:** U **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products	19-Jun-2019*	19-Jun-2019	N/A	H-E	Human Exposure: On 19 Jun 2019, the following human exposure was reported to Boehringer Ingelheim by the patient, a human of further unknown signalment. 19 Jun 2019: The patient accidentally squirted an unknown amount of FRONTLINE PLUS CATS (S40502AX) into their face. The owner is asymptomatic. No further medical information expected.

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						Route: Topical / Cutaneous **Was the product used ok?:** No (Human exposure (Off label use))					
19-Jun-2019	UHAE; 19US035374; WI; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** 53.00 Year(s) **Weight:** 165.000 Pounds	1	1	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 (Human exposure (Off label use))	19-Jun-2019	19-Jun-2019	N/A	H-E	Human Exposure: On 19 Jun 2019, the following human exposure was reported to Safety Call International (SCI) by the patient, a 53 year old, 165 pound, male. 19 Jun 2019: After applying FRONTLINE PLUS DOG 23-44 LBS (S61009) to his dog, the vial leaked and the patient got a small amount of product on his fingers and hands. The owner washed and rinsed his hands for approximately 10 minutes. No clinical signs were reported. No further medical information expected. Product quality: On 19 Jun 2019, the pet owner reported the following issue with FRONTLINE PLUS DOG 23-44 LBS (S61009). A vial purchased at the clinic appeared different from what was purchased in the past, but the difference was not confirmed. The owner mentioned that he previously purchased multi-dose packs, but it could not be confirmed if the vial in question was packaged individually or else if it was dispensed from a 3 or 6 pack. It was also noted that a small amount of product leaked from the vial after it was applied to the pet. Further details were not provided by the pet owner. Product return is not expected as it is unknown if the sample is still available for return. No further information.
20-Jun-2019	UHAE; 19US035738; OH; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** 30.00 Year(s) **Weight:** 175.000 Pounds	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure (Off label use))	20-Jun-2019	20-Jun-2019	N/A	H-E	Human Exposure: On 20 Jun 2019, the following human exposure inquiry was reported to Safety Call International (SCI) by the pet owner for themselves, a 30 year old, 175 pound, male human of further unknown signalment. 20 Jun 2019: The pet owner accidentally splashed an unknown amount of FRONTLINE PLUS CATS (lot number unknown) in his left eye while attempting to open the pipette. The pet owner does not wear contacts and did not rinse his eye. The pet owner is asymptomatic. No further medical information expected.
21-Jun-2019	UHAE; 19US036012; IL; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	0	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 (Human exposure (Off	21-Jun-2019	21-Jun-2019	N/A	H-E	Human Exposure: On 21 Jun 2019, the following event was reported by the pet owner for himself, a male of unknown signalment. 21 Jun 2019: The pet owner was applying FRONTLINE PLUS DOG 5-22 LBS (Lot Unknown) to his dog when the product got on his hand while he was opening it. He is asymptomatic. No further medical information 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
						label use))					
21-Jun-2019	UHAE; 19US036078; NY; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	0	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 (Human exposure (Off label use))	21-Jun-2019	21-Jun-2019	N/A	H-E	Human Exposure: On 21 Jun 2019, the following event was reported by the pet owner for herself, a female of unknown signalment. 21 Jun 2019: After applying FRONTLINE PLUS CATS (Lot Unknown) to her cat, a few drops got on the owner's finger. She washed her hands for 5-7 minutes, and is asymptomatic. No further medical information expected.
21-Jun-2019	UHAE; 19US036189; -; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	0	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 (Human exposure (Off label use))	21-Jun-2019*	21-Jun-2019*	N/A	H-E	Human Exposure: On 21 Jun 2019, the following human exposure was reported by the pet owner for herself, a female of further unknown signalment. Unknown date: The pet owner got an unknown amount of FRONTLINE (lot number unknown) (product unsubstantiated) on her hands when trying to apply the product. The owner washed her hands with soap and water and remained asymptomatic. The owner refused being transferred to Safety Call International for an unknown reason. No further medical information expected.
21-Jun-2019	UHAE; 19US036295; VT; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** 39.00 Year(s) **Weight:** 158 Pounds	1	0	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 (Human exposure (Off label use))	21-Jun-2019	21-Jun-2019	N/A	H-E	Human Exposure: On 21 Jun 2019, the following human exposure was reported to Safety Call International (SCI) by the pet owner for herself, a 39 year old, 158 pound, non-pregnant non-lactating female. 21 Jun 2019: The pet owner applied FRONTLINE PLUS DOG 45-88 LBS (S62408AX) to her dog. The dog rubbed the product on the pet owner's hand approximately 10 minutes prior to reporting the event. The pet owner washed her hands and remained asymptomatic. No further medical information expected.
24-Jun-2019	UHAE; 19US036463; MD; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	24-Jun-2019	24-Jun-2019	N/A	H-E	Human Exposure: On 24 Jun 2019, the following exposure was reported by the pet owner for herself, a female of unknown signalment. 24 Jun 2019: The pet owner applied FRONTLINE PLUS DOG 45-88 LBS (S61202AX) to her dog, and while opening the package got product on her hands. She is asymptomatic. No further medical information expected.

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

1. Due to system limitations, the end date is displayed as the first day of the current quarter, however only cases with a date first valid in the evaluated quarter are displayed.

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)
* indicates Approximate date or weight

In accordance with global BI policy, legal requirements, and regulations, BI records all adverse events (AE). Collection of an AE report does not constitute an admission by BI that our 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.

Date case Received	Case type; Case Reference; 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 (Human exposure (Off label use))					
25-Jun-2019	UHAE; 19US037087; OH; U.S.A	**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 (Human exposure (Off label use))	25-Jun-2019	25-Jun-2019	0 Day(s)	H-D	Human Exposure: On 25 Jun 2019, the following event was reported by the pet owner to Safety Call International (SCI) for herself, an adult female, other signalment unknown. 25 Jun 2019: A dose of FRONTLINE PLUS DOG 45-88 LBS (R62301AR) was applied to her dog about 1 hour ago. A few minutes ago, the caller's index finger came into contact with product on the dog. She briefly irrigated but does have a tingling sensation. No further medical information expected. UPDATE 3 Jul 2019: Per the patient, she washed the area thoroughly with dish soap, and the symptoms resolved after an hour or two. No further medical information expected.
27-Jun-2019	UHAE; 19US037801; NC; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** 61.00 Year(s) **Weight:** 170 Pounds	1	1	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 (Human exposure (Off label use))	27-Jun-2019	27-Jun-2019	0 Day(s)	H-D	Human Exposure 27-Jun-2019: Safety Call International (SCI) reported the following event. 27-Jun-2019 Patient reports she has gotten some of this product (FRONTLINE PLUS DOG 89-132) (R60402DR) on her hands while applying to her dog just prior to the call. Patient states she immediately washed her hands with soap and water. Patient states she isn't sure if it's her nerves, but she feels her throat may be feeling a little tight. Patient denies any shortness of breath. Provided patient with case number. Patient did seem very anxious from the beginning of the call. This patient has a history of allergies and asthma, taking an unknown number of medications to treat. UPDATE 28 June 2019: A call back from SCI was made to the patient and she reported that she developed a slight itch in the area after the original call was made. Symptoms resolved later in the day with no treatment. No other medical information is expected.
27-Jun-2019	UHAE; 19US037865; MA; U.S.A	**Sex:** U **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	2	0	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 (Human exposure (Off label use))	27-Jun-2019	27-Jun-2019	N/A	H-E	Human Exposure: On 27 Jun 2019, the following event was reported by a pet owner to Safety Call International (SCI) for her 2 children of unknown signalment. 27 Jun 2019: The pet owner applied a dose of FRONTLINE PLUS DOG (Unsubstantiated) (Lot Unknown) to her dog. The children touched the dog about 14 hours later after the product was dried and are asymptomatic. The children are healthy. The owner also reported a case for her dog, 19US037624. No further medical information expected.

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

1. Due to system limitations, the end date is displayed as the first day of the current quarter, however only cases with a date first valid in the evaluated quarter are displayed.

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)
* indicates Approximate date or weight

In accordance with global BI policy, legal requirements, and regulations, BI records all adverse events (AE). Collection of an AE report does not constitute an admission by BI that our 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.

D-A CASES

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
MARIA LUCIA S. C. PROCKNOR	07-23-2019		19BR001923

Address	Address
RUA ERNESTO ZWARG, 215 ITANHAÉM SP 11740000 Brazil	--UNKNOWN--
Phone # (13)34226154	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	01-10-2013	04-01-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
5.765/96		
A.I. (s) FIPRONIL SPOT ON DOG	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE SPOT-ON DOGS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19BR001923

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: As reported by the pet owner, Mile, a female Beagle of approximately 10.5 years old and 10 kg, received FRONTLINE PIPETTE (FL) (unsubstantiated) (lot and exp date unknown, topical, btw the shoulder blades), administered by the veterinarian on date not specified (1 Jan 2013 - chosen at random) for flea and tick prevention. Lack of efficacy is suspected because the pet got fleas and ticks after product administration. FL was used in the past with the same issue (dose frequency is unknown and date of first administration was not provided - 1 Jan 2012 chosen at random). The dog received FRONTLINE SPRAY on date not specified (1 Feb 2013 - chosen at random) and no more ectoparasites were reported. The environment was treated by a specialized company. This animal died on date not specified (unrelated death - 1 Jan 2014 - chosen at random). Similar case reported on 19BR001924. No further information is available.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 10.5 Year(s) - * Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 12 Month(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) FRONTLINE SPRAY.	List signs/symptoms/adverse effects Lack of efficacy Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: Patient weight: 10 kg			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19BR001923

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name MARIA LUCIA S. C. PROCKNOR	Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19BR001924
	Address RUA ERNESTO ZWARG, 215 ITANHAÉM SP 11740000 Brazil		Address --UNKNOWN--	
	Phone # (13)34226154		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 01-10-2013	Date registrant became aware of incident. 04-01-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 5.765/96	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL SPOT ON DOG	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE SPOT-ON DOGS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? No Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Between the shoulders (topical	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19BR001924

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Brazilian Terrier of approximately 10.5 years old and 10 kg, received FRONTLINE PIPETTE (FL) (unsubstantiated) (lot and exp date unknown, topical, btw the shoulder blades), administered by the veterinarian on date not specified (1 Jan 2013 - chosen at random) for flea and tick prevention. Lack of efficacy is suspected because the pet got fleas and ticks after product administration. FL was used in the past with the same issue (dose frequency is unknown and date of first administration was not provided - 1 Jan 2012 chosen at random). The dog received FRONTLINE SPRAY on date not specified (1 Feb 2013 - chosen at random) and no more ectoparasites were reported. The environment was treated by a specialized company. This animal died on date not specified (unrelated death - 1 Jan 2014 - chosen at random). Similar case reported on 19BR001923. No further information is available.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 10.5 Year(s) - * Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 12 Month(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) FRONTLINE SPRAY.	List signs/symptoms/adverse effects Lack of efficacy Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: Patient weight: 10 kg			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19BR001924

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
RENATA PONTES DE OLIVEIRA ALLUE	07-23-2019		19BR002332

Address	Address
RUA JOÃO GARCIA, 336 RIBEIRÃO PRETO SP 14093513 Brazil	--UNKNOWN--
Phone #	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	04-10-2019	04-25-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
4.913/94		
A.I. (s) FIPRONIL SPRAY	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE SPRAY	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	whole body	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19BR002332

Brief description of incident circumstances

Suspected adverse Reaction: As reported by the pet owner, a female Shih Tzu of 2 days old and unknown weight, was treated with FRONTLINE SPRAY (FL) (002/18, unknown exp date, topical, whole body), applied by the reporter on 9 Apr 2019, for tick treatment. One day after product application, the pet died. SLOE cases reported on 19BR002330 and 19BR002331. No further information is expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 2 Day(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 animal Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19BR002332

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name ANNE MARY unknown	Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19BR003120
	Address Brazil		Address --UNKNOWN--	
	Phone #		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 01-10-2019	Date registrant became aware of incident. 06-23-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 7.990/2001	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE PLUS DOGS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19BR003120

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one dog of unknown signalment received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Jan 2019 - chosen at random). Lack of efficacy was suspected because the pet was diagnosed with tick-borne disease. Details were not provided. FL was applied in the past, but the dose frequency is unknown. The dog died on date not specified. There is a cat in this household that was treated with FL and the owner still sees fleas (see case 19BR003121). No further information is available.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: Unknown - Sex : Unknown Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 5 Month(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lack of efficacy Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 animal Expose duration: 5 Month(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19BR003120

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Iris Hüsler	07-23-2019		19CH000035

Address	Address
Luzernstrasse 55a Derendingen 4552 Switzerland	--UNKNOWN--
Phone # 032 681 61 61	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	05-30-2019	06-04-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
56'044 001		
A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE COMBO CATS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation Topicals	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No		See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19CH000035

Brief description of incident circumstances

As reported by the attending vet, a cat, neutered female, bengal, 2 years old, 4.45 kg, in a good health condition, received FONTLINE COMBO for cats (BN and exp date unknown) on an unknown date, a Thursday (30 MAY 2019 was chosen by default), 1 dose spot on by owner. Then (otherwise not specified, 30 MAY 2019 was chosen by default) the dog experienced ptyalism and was more clingy. The cat disappeared 4 days after application and was found dead 6 days after applcation on a non-specified date (05 JUN 2019 was chosen by default). The vet's level of suspicion is medium. This is the extent of information available.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 2 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 0 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death Anxiety Hypersalivation		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 4.45 kg			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19CH000035

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Dr Teresa Perez		Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19CL000014
	Address Zoopolis Cosme Churruca 75, local 1 Concepción Chile			Address --UNKNOWN--	
	Phone #			Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 04-29-2019		Date registrant became aware of incident. 05-06-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 52	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL SPRAY	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE SPRAY	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19CL000014

Brief description of incident circumstances

On 02 MAY 2019 attending vet reported an adverse event resulting in death: Two stray kittens (age unknown, 0.7 kg, lactating kittens), that were found on the streets on 28 APR 2019, received FRONTLINE SPRAY (batch P03703A, expiry date 07/2019, route: topical, dose unknown), due to fleas, and an internal dewormed from another company (INVERMIC), both administered by the attending vet on 29 APR 2019. 30 minutes after product administration one kitten experienced lethargy and hypothermia. The kittens were bathed with warm water in order to eliminate the product. The kitten that presented lethargy and hypothermia started to tremble before dying. The other kitten never presented any sign (lethargy and/or hypothermia) and died abruptly. Both kittens died on 30 APR 2019.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: Unknown - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 0 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lethargy Hypothermia Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 animal Expose duration: 0 Day(s) Patient weight: 0.7 kg			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19CL000014

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Dr Nuria Mira	07-23-2019		19ES000311

Address	Address
CV Wapu's Veterinari C/ Peix, 11 Vendrell Tarragona 43700, Spain	--UNKNOWN--

Phone #	Phone #
977088914	

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	05-09-2019	05-10-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
1538 ESP	EU/2/97/004/006	
A.I. (s)	**A.I. (s)**	**A.I. (s)**
FIPRONIL 10%/S METHOPRENE 12% SPOT ON	Metacam meloxicam 5 mg/ml injection dog cat	
Product 1 name	**Product 2 name**	**Product 3 name**
FRONTLINE COMBO SPOT ON CATS	Metacam 5 mg/ml solution for injection for dogs	
Exposed to concentrate prior to dilution ?	**Exposed to concentrate prior to dilution ?**	**Exposed to concentrate prior to dilution ?**
Formulation	**Formulation**	**Formulation**
Topicals	Solution for Injection	

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Yes Intentional misuse No		See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19ES000311

Brief description of incident circumstances

Suspected Adverse Event: As reported by the attending vet, a 7-8 month-old and about 3 kg European male cat was anesthetized on 09MAY2019 for castration using 0.12 ml of Methadone 10 mg/ml (Esteve), 0.1 ml of Dormisan (medetomidine), 0.1 ml of Anesketin 100 mg/ml (ketamine) and 0.1 ml of Alfaxan 10 mg/ml (alfaxalone). After surgery, he also received 0.3 ml of amoxicillin (Syva) and 0.12 ml of Metacam 5 mg/ml (meloxicam). At the same time the animal also received Frontline Combo Spot-On Cats (batch and expiry date unknown) topically administered by the attending vet. After product administration the animal experienced stiffness limb and uncontrolled movements, ocular spasms and dilated pupils but there was no hypersalivation. The animal was treated with fluid therapy, atropine and REVERTOR 5 mg/ml (atipamezol) just in case the event was caused by the anesthesia although it was finally ruled out. The site of administration of the pipette was also washed. On 10MAY2019 the animal improved but was apathetic and continued with ocular spasms. On 13MAY2019 he was fine but pupils were still dilated and had ocular spasms. On 15MAY2019 he was even better although he still had the tic in the eye and fell down after 3-4 steps. Blood test could not be performed as the animal was feral, and was sent back to the animal shelter. That day was treated with corticoids. Infectious disease was also suspected although no blood test could be performed. On the 17th May 2019, the animal was admitted in a vet hospital since it did not blink and had inflamed the left maxillar. A blood analysis was performed and showed mild leukocytosis, neutrophilia and high levels of BUN, P, PT and globulins. A FeLV / FIV test was performed and showed negative results. The eye analysis was normal. On the 19th May 2019, the animal started linking and was improving but prsented convulsions. On the 20th May 2019, the animal was euthanized (intracardiac) due to a worsening. This animal came from an animal shelter together with another female dog that also received the same treatment. UPDATE 31MAY2019: The results from the necropsy were received and showed hepatic lesions of a moderate nature. These alterations (hydropic degeneration and multifocal necrosis) were nonspecific and can not be related to a specific agent. Based on the clinical symptoms of the animal and absence of lesions in the central nervous system, it seemed that the administration of any of the medications applied may have been the cause of said symptoms. Hemorrhage resulting from hepatic rupture was also moderate to severe, occurring a few minutes or hours before the death of the animal, and although it may be an element that significantly aggravates the clinical symptoms, by itself it did not seem to present sufficient entity as to cause the death of the animal. The animal also presented an ulcer observed in the left upper lip is of moderate character, and although it did not seem to directly compromise the animal's life, it could cause a febrile state or difficulty feeding that predisposed the animal to other pathologies, and the cause of the thinness that it presented. This type of ulcer could have different causes (traumatic, bacterial, viral or idiopathic). Renal lesions corresponded to old infarcts, which however did not seem to alter the functionality of the rest of the renal parenchyma without lesions. Finally, no lesions indicative of FIP were observed in the animal. On the 03JUN2019, the necropsy results were commented with vet, who did not know exactly which product could be responsible for the animal's events. As the animal had some renal disorders, this could also affect to the drugs excretion.

Demographic information: Age: 7 - 8 Month(s) Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 0 Day(s)	

Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Fluid therapy, atropine	List signs/symptoms/adverse effects Muscle stiffness Dyskinesia Blepharospasm Mydriasis Lethargy Ataxia Palpebral disorder NOS Oedema NOS Convulsion Leucocytosis NOS Neutrophilia Increased blood urea nitrogen (BUN) or creatinine Elevated globulins Other abnormal test result NOS *See continuation page*	If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 3 kg*		
Human severity category D-A		

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19ES000311

* approximate

Version : unapproved

Page 3. List signs/symptoms/adverse effects - continued

Hepatic necrosis

Hepatopathy

Stomatitis

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Raphaël BOULANGER	07-23-2019	Dr Anthony GUIHNEUF	19FR000475

Address	Address
4C Hameau de Kerleit PLEVIN 22340 France	Clinique Vétérinaire de Rostrenen 6 rue Joseph Pennec ROSTRENEN 22110 France
Phone #	Phone # 02 96 57 42 00

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	04-06-2019	04-09-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
FR/V/1803950 2/1994		
A.I. (s) FIPRONIL SPRAY	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE SPRAY POMPE (0.5 ML - 1.5 ML)	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Intentional misuse No	Whole body	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19FR000475

Brief description of incident circumstances

Suspected Adverse Event: As reported by the animal's owner, seven 1-month-old females and males French Bulldog puppies, weighing 600 to 900 g, in an unknown condition, received FRONTLINE SPRAY POMPE (BN: S00708A, Exp. date: FEB 2021) administered topically all over the body by the owner on 06 APR 2019 for flea treatment (it is unknown if the recommended dose (6 sprays/kg) was respected). Then (exact time to onset not specified), all puppies displayed sudden lethargy and dyspnoea. On the 06 and 07 APR 2019, 3 first puppies died. On 08 APR 2019, the 4 remaining puppies were brought to the vet: mention of blood in faeces and hyperthermia. Floryboost and Marbocyl were prescribed. On 08 and 09 APR 2019, 3 other puppies died. On 10 APR 2019, only one alive puppy. Investigation: the vet sent faeces samples for analysis (nos). Autopsy was performed on one dead pup (unknown results). Note: The mother of the litter died on 01 APR 2019 of gangrenous mastitis. The owner had brought the animals to the clinic for routine check-up. The vet found a flea and advised to administer Frontline SPRAY POMPE. Note: the vet reported that the animals were suffering from a disease at the time of the administration of the product but no more information was provided.

ED_005739D_00014404-00598

Demographic information: Age: 1 Month(s) - Sex : Mixed Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Floryboost and Marbocyl	List signs/symptoms/adverse effects Hyperthermia Death Lethargy Dyspnoea		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per Unknown Expose duration: 0 Day(s) Patient weight: 0.6 - 0.9 kg			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19FR000475

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Ms Patricia LANE		Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19FR000701
	Address France			Address --UNKNOWN--	
	Phone #			Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 03-27-2019		Date registrant became aware of incident. 05-28-2019	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) FR/V/2879019 8/2003		EPA Registration # (Product 2)		EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON		A.I. (s)		A.I. (s)
	Product 1 name FRONTLINE COMBO SPOT ON CHIEN S		Product 2 name		Product 3 name
	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?
	Formulation		Formulation		Formulation
Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use		Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No				
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances			

Version : unapproved

Internal ID # 19FR000701

Brief description of incident circumstances

ADVERSE REACTION and LACK OF EFFICACY case: As reported by the owner, a 4 year-old (approx. age) crossbred Tulear Cotton (sex and weight unknown) had received topically FRONTLINE COMBO SPOT ON CHIEN S (BN: S62404AX and exp. date: AUG 2021) administered by the owner in MAR 2019 (no mention of exact date of treatment, supposedly in MAR). On 27 MAR 2019, a tick was found on the dog. On 30 MAR 2019, the dog was taken to a vet in emergency (clinical signs nos), where piroplasmosis was confirmed (nos) and treated (nos). On 01 APR 2019, a stroke and a pancreatitis were diagnosed (nos). The dog was euthanized on 02 APR 2019. The owner mentioned that her dog could have lived 6 to 12 months again (nos). Note: According to the owner, the dog was treated with FRONTLINE its whole life and never had ticks before the one involved in this AE. This case is linked with the case 19FR703. Case considered as both SLOE (one tick observed) and AE (stroke and pancreatitis), therefore both problem types were chosen. Cases initially reported as a comment in a merchant website (then owner directly contacted by PV service to obtain further information).

Demographic information: Age: 4 Year(s) - * Sex : Unknown Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms:	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lack of efficacy Pancreatitis Cerebral vascular accident Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19FR000701

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Mrs Pascale GRAVELAS	Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19FR000718
	Address 10 La Bouloie PARLY 89240 France		Address --UNKNOWN--	
	Phone #		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 05-11-2019	Date registrant became aware of incident. 06-03-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) FR/V/3168431 0/2003	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE COMBO SPOT ON CHAT	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Between the shoulders (topical	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19FR000718

Brief description of incident circumstances

Suspected Adverse Event: As reported by the animal's owner, a 11-year-old female cat in good condition received one pipette of FRONTLINE SPOT-ON CHAT (BN: S40906AW, Exp. date: JUN 2021) administered topically by the owner between the shoulders at the base of the neck on 11 MAY 2019. After product administration (unknown time to onset), the animal experienced decreased appetite, smaller eyes (encoded as "Third eyelid extrusion" into Veddra), slightly greasy hairs all over the body, and low pitched mewing. It did not want to come home and died on 28 MAY 2019. The animal was not seen by a vet but the owner is convinced that death is consecutive to product administration.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 11 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 0 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Anorexia Protrusion membrana nictitans Hair change Vocalisation Dysphonia Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Once Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19FR000718

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Mr S F		Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19IT000061
	Address Italy			Address --UNKNOWN--	
	Phone #			Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 05-04-2019		Date registrant became aware of incident. 05-06-2019	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 103647018		EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON		A.I. (s)	A.I. (s)	
	Product 1 name FRONTLINE COMBO SPOT ON GATTI		Product 2 name	Product 3 name	
	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	
	Formulation Topicals		Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Intrascapular (Parenteral		Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No				
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances			

Version : unapproved

Internal ID # 19IT000061

Brief description of incident circumstances

As reported by the owner, a cat, female, intact, 10 moths old received 1 dose of Frontline Combo Spot On Cats on 03/05/2019 in the morning administered by the owner.
24 hours after product administration the animal experienced depression and lack of appetite.
On 05/05/2019 (Sunday) the owner found the cat died

The owner reported that the cat go outside and in his opinion the cat found some poison there

Demographic information: Age: 10 Month(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lethargy Anorexia Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: Patient weight: --UNKNOWN--			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19IT000061

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Soukaina Imazzi	07-23-2019		19MA000001

Address	Address
MCI Santé Animale Lot 157, ZI Sud-Ouest P.O. Box 278 Mohammedia 28810, Morocco	--UNKNOWN--
Phone #	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	05-05-2019	05-16-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
1890.2/17		
A.I. (s) FIPRONIL 6.01% / PERMETHRIN 44.88% SPOT ON SOLUTION	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE TRI-ACT	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation Solution (Non-Sterile)	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No		See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19MA000001

Brief description of incident circumstances

As reported by the attending vet, a dog, female, pregnant, 3 years old, 8 kg, in a good health condition, received FRONTLINE TRI-ACT S (BN R92105AC, exp date 01 MAR 2020), one pipette topically, by vet for antiparasitic treatement, on an unknown date (17 APR 2019 was chosen by default) for the first time. 15 days after treatment the dog gave birth to 6 puppies. 4 to 7 days after birth symptoms of intoxication (no more details) were observed and the 6 puppies died. The vet's level of suspicion is high. This is the extent of information available.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 3 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms:	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Perinatal mortality		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 8 kg			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19MA000001

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Alyce Parry	Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19NZ000131
	Address Animates Vetcare Botany 12 Amera Place Botany Auckland , 2013 New Zealand		Address --UNKNOWN--	
	Phone # +6492714646		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 05-07-2019	Date registrant became aware of incident. 05-08-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) A9008	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE PLUS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Between the shoulders (topical	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19NZ000131

Brief description of incident circumstances

As reported to me by a veterinary nurse, two rabbits, one female and one male (furthers details unknown) were treated on 6 May 2019 with Frontline Plus (exact product unknown) and on 8 May 2019 they were brought in for veterinary exam due to one rabbit having a short seizure and both rabbits off food. The second rabbit had seizures starting 9 May 2019. Both rabbits were treated with midazolam and hospitalized for syringe feeding and monitoring. I contacted the clinic for further information on several occasions but I was unable to speak to the team leader until 17 May 2019 at which time I was told the rabbits had been euthanized on 10 May 2019. I have repeatedly requested more information but have been unsuccessful at this time.
Update MF 28 May 2019: Recieved adverse event report. I have updated patient field, product field and Veddra codes. The product assessment remains the same.
Updated narrative: Littermates, one male and one female intact, Mini Lop x Rex, 7 months old, weighing 1.3kg were treated at 2pm on 6 May 2019 each with a pipette of Frontline Plus for Cats topically between the shoulder blades, batch and expiry unknown, for flea prevention. The following day on 7 May both rabbits were noted to be not right and under veterinary advice were both washed and given activated charcoal. That evening both rabbits started tremors. The male had several seizures throughout 8-9 May and died at 10:25pm on 9 May. The female had tremors on 8 May and seizures through 9 - 11 May and died 5:30am on 11 May. The rabbits were treated with midazolam as required to control seizures and given symptomatics care to ensure drinking and eating.

Demographic information: Age: 7 Month(s) - Sex : Mixed Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) midazolam	List signs/symptoms/adverse effects Anorexia Convulsion Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 1.3 kg			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19NZ000131

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Linnea Warthel	Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19SE000063
	Address Sweden		Address --UNKNOWN--	
	Phone # +46738490580		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 05-02-2019	Date registrant became aware of incident. 05-04-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 13130	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL SPOT ON CAT	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE SPOT-ON VET CATS 100 MG/ML SPOT ON	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ? Unknown to Company	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Between the shoulders (topical	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19SE000063

Brief description of incident circumstances

Suspected AE. As reported by the animal owner, a 3-year old male neutered Domestic shorthaired cat (weight 3.5-4 kg) with pre-existing heart- and kidney disease since 1.5 years (fair condition) received FRONTLINE VET SPOT-ON 100 mg/ml (LOT unknown) 1 dose topical between the shoulderblades administered by the owner on 02 MAY 2019 at approx. 8 PM. In the night after product administration the cat acted weird, walked around vocalising and wanted to be with the owner or lay itself to rest in strange places. At approx. 00.45 the cat was confused and walked into the walls. The cat did not eat or drink. The reaction continued on 3-MAY and the owner took the cat to the vet. The cat was hospitalised over night (the owner did not know what the cat was treated with). On the 4-MAY the cat was euthanized. The cat had been an indoor cat until 2 weeks prior to the event, the owner bought FRONTLINE for prophylactic use. The owner asked at pharmacy if the product could be used with concurrent heart- and kidney disease and the pharmacist said yes. Since approx. 1.5 years the cat was treated with heart medication tablet once daily and kidney medicaiton oral solution once daily in the food (the owner did not know the name of the products).
2019-06-14: Follow up from MPA: MPA causality has been added and "heart medication" and "kidney medication" was removed from the structured field since the product or substance was not known. UPDATE 20-JUN-2019: MAH updated assessment.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 3 Year(s) - Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 4 Hour(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) The cat was hospitalized	List signs/symptoms/adverse effects Lethargy Hyperactivity Disorientation Emesis Death Anxiety Impaired vision Vocalisation Anorexia Adipsia		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 3.5 - 4 kg			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19SE000063

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Katja Salén		Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19SE000120
	Address Sweden			Address --UNKNOWN--	
	Phone #			Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 12-31-2015		Date registrant became aware of incident. 06-29-2019	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 13130		EPA Registration # (Product 2)		EPA Registration # (Product 3)
	A.I. (s) FIPRONIL SPOT ON CAT		A.I. (s)		A.I. (s)
	Product 1 name FRONTLINE SPOT-ON VET CATS 100 MG/ML SPOT ON		Product 2 name		Product 3 name
	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?
	Formulation		Formulation		Formulation
Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use		Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No				
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances			

Version : unapproved

Internal ID # 19SE000120

Brief description of incident circumstances

As reported by an animal owner, a 'Tigeröga' a male Maine coon cat (age and bodyweight unknown) received FRONTLINE VET (unknown if spot-on or spray), administration details not specified, administered by the owner on unknown date. The cat became ill, the owner reported that the cat had a 'mysterious, unidentifiable disease' and the veterinarian could not figure out what was wrong. The cat was treated for a long time with drip and cortisone and several tests were done (not further specified). The owner reported that the cat was thin and miserable and that it died (unknown if euthanised) on unknown date. The owner reported that she had to wait 3 years until she could buy a new Maine coon cat ('Maximilian'), which received FRONTLINE VET and showed same signs as Tigeröga, this was when the owner realized why Tigeröga was ill. The new cat (Maximilian) is reported in SWE-BIAHPV1P-19SE000121. MAH comment: Based on the received information, date of administration and signs has been estimated to 2015. The MAH tried contacting the owner for more information but at the time of the report no more information was available.

Demographic information: Age: Unknown - Sex : Male Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: Unknown	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Drip and cortisone (not	List signs/symptoms/adverse effects Death Malaise Weight loss		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 animal Expose duration: Unknown Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19SE000120

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Inthupa Kitinunt		Submission date. 07-23-2019	Contact person (if different than reporter) Ms.Nan J	Internal ID # 19TH000006
	Address Thailand			Address Bangkok Thailand	
	Phone #			Phone # +66819515757	
	Incident Status: New If update,include date of original submission	Location and date of incident. 04-16-2019		Date registrant became aware of incident. 06-04-2019	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 1358/2554		EPA Registration # (Product 2)		EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON		A.I. (s)		A.I. (s)
	Product 1 name FRONTLINE PLUS CATS		Product 2 name		Product 3 name
	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?
	Formulation Topicals		Formulation		Formulation
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).		Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No				
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances			

Version : unapproved

Internal ID # 19TH000006

Brief description of incident circumstances

A 1-month-old Domestic Short Hair breed cat, Name is Chakeaw had both hindlimb hyperextension after her mother used Frontline Plus Spot On, which her owner bought from pet shop and didn't know lot number/expire date. Before using drug This cat, her mother and her sister is normal but in the same day after using, the owner found that Chakeaw had abnormal sign while her mother and her sister is normal (Only her mother used the product, but not sure if both kitten expose to the product or not). Next day(17/4/19), the owner taked her to Animal hospital. Veterinarian found she had normal heart sound & normal lung sound and no fever, vet gived her 10 ml Lactate Ringer Solution and monitor. 18/4/19 Veterinarion gived vitamin B, 0.5 ml Amoxiclave PO bid, Prednisolone 0.01 ml (SC) and monitor. 19/4/19 Chakeaw can stand by herself and had normal balance, so the veterinarian gived vitamin B and antibiotic ongoing and sent her back to home. After 10 days, the owner called to vet and informed that she died without any information support.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 1 Month(s) - Sex : Female Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Lactate Ringer Solution,	List signs/symptoms/adverse effects Hyperextension Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 animal Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19TH000006

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Elinor Jones	07-23-2019		19UK001228

Address	Address
Medivet Llandaff North 4 Evansfield Road Cardiff, South Glamorgan CF14 2FA United Kingdom	--UNKNOWN--

Phone #	Phone #
01446 774016	

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	04-07-2019	04-08-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
Vm 08327/4133		
A.I. (s) FIPRONIL SPOT ON CAT	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE SPOT ON CAT	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	Unknown use	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19UK001228

Brief description of incident circumstances

As reported by the attending veterinary surgeon, Mansfield, a 9 year old male neutered Domestic Short Haired feline, weighing 4 kg and in unknown condition, was administered FRONTLINE SPOT ON CAT (batch S20306AW, expiry FEB 2021) topically to an unknown site, by the animal owner on 07 APR 2019 as a preventative treatment. The animal owner reported that the rescue centre from which they got the animal had used FRONTLINE on him previously. An adverse reaction was reported to occur on the same day as product use. The animal was seen by the attending vet on 08 APR 2019 for a check up post adverse reaction. The appointment was made for 11:30 due to hypersalivation. The examination was unremarkable - heart rate was 140, respiratory rate was 20 - and there was some slight hypersalivation. It was suggested by the animal owners that the animal licked the application site. The animal owners had washed the application site within 20 minutes, but not the paws, just the back of the neck. The animal was walking around fine in the consultation room, there were no neurological signs and there were no obvious application signs, no greasy marks on the hair or skin noted by the vet. Atropine injection was declined by the animal owners and they were going to monitor. The vet advised that if there were any tremors or wobbling to bring the animal back straight away. Ninety minutes after the consult, the animal owner called the practice reporting that the animal had a weird neurological episode like it was fighting - clawing at the air, biting, attacking everything - and then died.
UPDATE: 22 MAY 2019: QA results received: Investigation completed for FIPRONIL SPOT ON CAT Lot S20306AW, expiry 2021-02-28. Case investigated by France - Toulouse. A product quality complaint for FRONTLINE SPOT ON CAT lot number S20306AW was received by BIAH QA on 08th Apr 2019. The complaint description is: adverse reaction. This is the first complaint regarding this defect for this batch. The retention
sample is conform but will not respond to an adverse reaction. Batch record review: Manufacturing date: 05/03/2018 - Expiry date: NA - Manufacturing quantity: 1199 liters. No deviation and observation are associated to this batch and this batch was not concerned by any change control. The results of QC testing are conform at specifications. All parameters verified during manufacturing of this batch of bulk are conform. No root cause could be identified on Toulouse plant. 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.
This defect remains isolate and rare. This complaint is categorized major with no impact for the market. This complaint is not justified.

Demographic information: Age: 9 Year(s) - Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms:	

Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Hypersalivation Aggression Aggression Neurological disorder NOS Death	If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 animal Expose duration: Patient weight: 4 kg		
Human severity category D-A		

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19UK001228

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Becky O'Dowd	07-23-2019		19UK001340

Address	Address
SPA Veterinary Services Ltd 3 School Lane, Quedgley Gloucestershire GL2 4PJ United Kingdom	--UNKNOWN--
Phone #	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	05-27-2015	04-18-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
Vm 08327/4213	EU/2/97/004/046-048	EU/2/97/004/006
A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s) Metacam meloxicam 2.5 mg chewable	A.I. (s) Metacam meloxicam 5 mg/ml injection dog cat
Product 1 name FRONTLINE COMBO SPOT ON DOGS L	Product 2 name Metacam 2.5 mg chewable tablets for dogs	Product 3 name Metacam 5 mg/ml solution for injection for dogs
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation Chewing tablet	Formulation Solution for Injection

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Intentional misuse No	Unknown use	See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19UK001340

Brief description of incident circumstances

As reported by the attending veterinary surgeon, Harry, born 27 NOV 2011 a male Labrador Retriever canine (signalment otherwise unknown) was administered FRONTLINE COMBO SPOT ON DOG L (batch and expiry unknown) (details unknown) on 27 MAY 2015 for an unknown indication. The animal came into the practice with a history of skin problems from the previous practice, that suggested atopic dermatitis. The vet notes that this was not that severe at this stage and that allergy tests pointed to storage mites and not grasses etc, yet Summer weather brings out the worst pruritus, possibly due to heat etc. The animal has had an incomplete diet trial and has previously used Cortavance and Malaseb. The animal is fine in Winter, and managed ok. The animal's feet were quite red and so sellotape was used to check for Malassezia and a trial of Apoquel 16 mg was prescribed, along with Malaseb shampoo and the FRONTLINE COMBO SPOT ON DOG L. The animal was given Nobivac L4 and Nobivac KC on this day. The animal remained on Apoquel 16 mg.
On 27 MAY 2015 results from the swab taken from the ear showed very few Malassezia and the canals looked ok. The sellotape from the feet showed scant Malassezia.
On 10 JUN 2015 the animal came in for a check as was off his legs earlier, but was then fine. The vet queried a possible seizure.
On 24 JUN 2015 the animal received another dose of Nobivac L4.
On 12 AUG 2015 the animal was dispensed Bravecto 100 mg and Milpro 12.5 mg / 125 mg tablets.
On 06 OCT 2015 the animal came in for a check up and was doing really well. All the target areas were very comfy. The animal owner tried to stop the Apoquel but with no joy. More Apoquel 16 mg was dispensed.
On 22 DEC 2015 the animal was dispensed Bravecto 100 mg and Milpro 12.5 mg/ 125 mg.
On 18 JUL 2016 the animal was due for a booster and medication check but 2 nights ago (16 JUL 2016) and 10 weeks previously (09 MAY 2016) the animal had had what sounded like an exercise induced seizure lasting 1 to 2
minutes. The animal was well in between. Bloods were taken. The results were reported on 22 JUL 2016 and proBNP was ok and nothing on biochemistry to chase and so the vet suggested waiting and watching.
On 01 AUG 2016 the animal received Nobivac DHP, Nobivac L4 and Nobivac KC.
On 03 AUG 2016 the animal was prescribed Bravecto 1400 mg.
On 25 JAN 2017 the animal was checked for repeat prescriptions. The animal was doing well but a change in diet seemed to cause a flare up and the animal owner is unable to reduce the dose for very long at any time of the year. The animal's heart was ok on auscultation and there were no further 'fits' reported.
On 18 JUL 2017 the animal received Nobivac L4 and Nobivac KC. The animal had moderate bilateral otitis externa and was prescribed a course of Canaural. Bloods were taken and results showed nothing to stop using the Apoquel.
On 28 JUL 2017 the animal had a cytology of an ear swab taken as the animal owner had not really given a decent course of drops and the ears were not 100 percent. The vet reports that it was also possible that the animal had a fit a few days ago (estimated 25 JUL 2017). Results from the cytology showed a few rods in the left sample and nothing much in the right.
On 22 SEP 2017 the animal was prescribed Bravecto 1400 mg and Milpro 12.5 mg/ 125 mg.
On 26 JAN 2018 the animal came in for a check up. There was sludgy otitis externa on the left ear and the right ear was clean. The animal owner had been using coconut oil. Vetruus Otidine was prescribed.
On 08 FEB 2018 the animal's ear was much less sludgy but there was still a pale grey discharge, which was quite watery with some smell. Cytology showed reasonable numbers of rods and so Aurizon was added with the Otodine for 2 weeks.
On 24 FEB 2018 the animal had a recheck and the left ear was nice and clean. There was a definite improvement and the vet elected now to move to Otodine as the ongoing cleaner. Otodine was prescribed.
On 29 MAR 2018
the animal came into the practice as he had a swollen area under the right chin. There was purulent discharge from various deeper areas when squeezed. The vet suspected a deep follicular pyoderma and dispensed Kesium Chewable Tablets 500 mg and Prednisolone 5 mg tablets.
On 12 APR 2018 the animal was loads better. The animal owner will use some topical Hibiscrub for a week and then taper the Prednisolone off over 12 days.
On 24 JUL 2018 the animal was vaccinated with Nobivac L4 and Nobivac KC and was prescribed Bravecto 100 mg and Milpro 12.5 mg / 125 mg.

See continuation page

Demographic information: Age: 3 Year(s) - Sex : Male Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms:	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Vetruus Otodine,	List signs/symptoms/adverse effects Other ear disorder NOS Skin disorders NOS Loss of consciousness Convulsion Dermatitis and eczema Otitis externa Abnormal cytology Otorrhoea Bacterial skin infection Lameness Bone and joint disorder NOS Joint pain NOS Arthritis Melaena Vocalisation *See continuation page*		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: per Unknown Expose duration: Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19UK001340

Version : unapproved

Row 3 : Incident Circumstances - continued

On 03 OCT 2018 the animal was prescribed Milpro 12.5 mg/ 125 mg and Bravecto 100 mg.
On 07 DEC 2018 the animal was prescribed Vetruus Otodine Solution.
On 29 MAR 2019 the animal was seen at the practice as he had been lame on the left hind since last night (28 MAR 2019). The animal was not really weight bearing today but was otherwise bright and happy. On examination the vet could feel cranial draw and the animal was not keen on hip extension. The vet was worried about cruciate damage and advised NSAIDs over the weekend. The animal was dispensed METACAM 2.5 MG CHEWABLE TABLETS FOR DOGS (batch and expiry unknown) to be given 1 and a half tablets once daily with or after food.
On 02 APR 2019 the animal had full cranial draw in the left stifle. The animal was walking a little better and was in good spirits, but the knee was very unstable and needed surgery. The animal was prescribed more METACAM 2.5 MG CHEWABLE TABLETS.
On 12 APR 2019 the animal came in to the practice and was given an Anaesthetic - ACP, Buprelieve, Propofol and Isoflurane. The animal also received Vetivex 11 fluids. There was full cranial draw in the left stifle with clunking on manipulation. The X-rays showed joint effusion but nothing sinister. A lateral parapatellar arthrotomy and TTA were carried out. The animal was given a second injection of Buprelieve as well as Synulox, Marcain and METACAM 5 MG/ML SOLUTION FOR INJECTION (batch
and expiry unknown). The animal was sent home with Kesium Chewable tablets 500 mg, Pardale V Tablets and the METACAM 2.5 MG CHEWABLE TABLETS from previously.
On 13 APR 2019 the animal was whingey and so Buprelieve was supplied and the animal owner was taught how to inject the animal every 6-8 hours.
On 15 APR 2019, at the point of discharge, the nurse was removing the canula from the right cephalic vein and it broke off. The vet cut down onto the vein under local anaesthetic and removed the piece of canula. There was no bleeding and Supramid was put in the skin. The vet also advised to reduce the dose of Buprelieve to 2.5 ml every 8 hours if needed. The animal had had black faeces with red inside, and yesterday (14 APR 2019) was off food, but the animal was eating today. The vet advised to stop the METACAM and to start Omeprazole 10 mg. Pardale V and Buprelieve were continued as needed.
On 16 APR 2019 the animal owner rang as the animal was shaking and seemed to be not with it. The animal then had nasty black diarrhoea in the garden and vomited food. The animal came in and was very quiet, slightly shaky, unable to get up, with pale mucous membranes, a painful abdomen and a temperature of 39.9. The animal had had Pardale at 5 am, 1 pm and 7 pm and METACAM at 7 am with food. The animal was admitted and given Vetivex 11 fluids, Cerenia, Ranitidine, Synulox and Buprelieve but no Omeprazole as the animal was too sleepy to take tablets. The animal was very flat, with a temperature of 39.1 and salivation. The animal was given a bolus of fluids because the drip had come out of the right forelimb. Bloods were run and were supportive of gastric issues - albumin was slightly low and the animal had mild non-regenerative anaemia. Haematology results showed Haematocrit to be 0.353 (0.373-0.617), MCV to be 52 (61.6-73.5), MCH to be 19.3 (21.2-25.9), RDW to be 22.6 (13.6-21.7), Reticulocyte to be 16.5 (22.3-29.6), Neutrophils to be 0.21 (2.95-11.64, Monocytes to be 4.49
(0.16-1.12) and Eosinophils to be 0.01 (0.06-1.23). On Biochemistry Total Protein was 50 (52-82) and Albumin was 21 (23-40).
On 17 APR 2019 the animal had had a fair amount of vomiting overnight, with the occasional wet cough. An abdominal scan confirmed free fluid and a tap was taken. Slightly brown / blood tinged fluid was obtained. Slides were made and these confirmed the presence of toxic neutrophils and occasional bacteria. The animal owner elected to put the animal to sleep. The animal was given Lincoject, Paracetamol and Buprelieve in the day and then later Dolethal for euthanasia. A post mortem was performed and a 1 cm round perforation in the stomach fundus was found, as well as another split above this. A large pouch had developed along the length of the stomach as the omentum had covered this area (and presumably filled and stretched with time). The pouch appeared to be chronic with a very thick lining. The pouch was the size of the stomach and full of brown fluid. At one end there was a fresh small hole and the omentum had formed a band from this point to the bladder and attached in several places to the intestines (though there were no ruptures). There was no obvious cause ie no foreign body or evidence of neoplasia.
UPDATE 24 MAY 2019: QA results received. Investigation completed for Metacam meloxicam 2.5 mg chewable Lot Unknown, expiry UNKNOWN. Complaint clarified as: Adverse Event; Adverse reaction.

An investigation was conducted following the 5M method. Over the last 12 months (26Apr18 to 26Apr19) this is the thirteenth complaint received for this defect in Metacam product. No specific documentation could be reviewed since no batch number was provided. All the raw materials used in the manufacturing and packaging for this product meet all the quality specifications and are used before their expiry date. All the activities performed according to GMP's and manufacturing procedures. No deviations or problems have been reported during the processes
for this product that could be related with the described event. The opening torque test was performed every hour, by taking 10 samples and measuring the opening torque. The results must be within specified range of 6 to 30 lb/in for individual results and for the average results taken every hour, these must be within 8 to 12 lb/in parameter. The finished goods packaging was performed in one of the two lines available: Serpa or Semi-automatic packaging lines. The equipment used in the manufacturing and packaging processes is qualified. The complaint sample was not returned to the manufacturoing site to be evaluated. No specific retain sample could be reviewed since no batch number was provided by the customer. According to the investigation performed, there is not assignable root cause to any of the processes performed at the manufacturing site. Previous records were classified as not confirmed since not assignable root cause to any activity performed at the manufacturing site was found. CAPA Plan is not required since the root cause is determined to be outside of the manufacturing site control. In regard of the Impact Assessment, since the root cause was determined to be outside of the manufacturing site control, an impact on other units of the same batch or other batches of product is not expected. This complaint is categorized as NOT JUSTIFIED.
UPDATE 17 JUN 2019: Following internal review, the following corrections were noted: On 27 MAY 2015 the dog was also dispensed '2 x Milbemax Chewy Tablets Dog 5-25 (4)' with the instructions to take 2 tablets every 3 months. The dog was dispensed Bravecto 1000 mg, not 100 mg as previously reported, on 12 AUG 2015, 22 DEC 2015, 24 JUL 2018, 03 OCT 2018. No new information received.
UPDATE 07 JUN 2019: QA results received. Investigation completed for Metacam meloxicam 5 mg/ml injection dog cat Lot Unknown, expiry UNKNOWN. Case investigated by 3PM Europe - AH. Since the manufacturing site does not have any information
about the batch of the complaint, it is not possible to review the batch documentation. The batch had to be manufactured between 2016 and 2019 since the event occurred in April 2019 and the shelf-life of the product is three years. The PQR of the investigation period do not indicate any quality issues which might have led to this adverse event. No batch has failed to meet established specifications in the batches manufactured between 2016 and 2019. The results of the stability ongoing studies have been reviewed and are compliant. This is the ninth complaint relating to Metacam 5 mg/ml solution for injection related to an adverse event received in Labiana during the last three years. None of them has been confirmed. No sample has been received for this complaint and we do not have any information about the batch number so no sample analysis can be carried out. According to the investigation, no root cause that could have led to the complaint adverse event has been found. Therefore, the complaint is considered as "not confirmed". No market action is required because from a technical point of view the complaint is "not confirmed". The initial complaint category is kept because classifies the complaint as "critical".

Page 3. List signs/symptoms/adverse effects - continued

Digestive tract haemorrhage NOS

Systemic disorder NOS

Impaired consciousness

Anorexia

Haemorrhagic diarrhoea

Emesis

Malaise

Ataxia

Pale mucous membrane

Abdominal pain

Hyperthermia

Lethargy

Hypersalivation

Hypoalbuminaemia

Anaemia NOS

Cough

Other abnormal test result NOS

Abnormal necropsy finding

Death

Neutropenia

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Sarah Sadler	Submission date. 07-23-2019	Contact person (if different than reporter) Gemma Unknown	Internal ID # 19UK001584
	Address United Kingdom		Address Sleaford Vets Westbanks, Sleaford Lincolnshire NG34 7PQ United Kingdom	
	Phone # 07837292222		Phone # 01529 414525	
	Incident Status: New If update,include date of original submission	Location and date of incident. 05-16-2019	Date registrant became aware of incident. 05-18-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) Vm 08327/4267	EPA Registration # (Product 2) Vm 08327/4133	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s) FIPRONIL SPOT ON CAT	A.I. (s)
	Product 1 name FRONTLINE PLUS SPOT ON CATS	Product 2 name FRONTLINE SPOT ON CAT	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19UK001584

Brief description of incident circumstances

As reported by the animal owner and attending vet, Sparkle, a 12 year 2 months old female neutered cat weighing 3.03 kg, was treated with FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown) at an unknown dose, route and frequency on 16 MAY 2019, administered by the animal's owner. The owner has been using FRONTLINE (assumed spot on cat) on the cat for years and never had any problems with it. On 16 MAY 2019 the owner had bought FRONTLINE PLUS SPOT ON FOR CATS instead of the usual FRONTLINE FOR CATS. The product was applied by the owner in the usual way. Within 2 hours the cat started having seizures. The cat was taken to the vet, put on oxygen and fluids, then released. The next day she had another seizure and her kidneys failed and they had to have her put to sleep. On 20 MAY 2019 the attending vet reported that on 16 MAY 2019 (Thursday night) the animal owner heard the animal vocalising and then found it collapsed in the bathroom after having applied FRONTLINE PLUS earlier. The animal appeared to be in respiratory distress. On clinical examination all was ok, with no significant abnormalities found, and the animal had made a pretty good recovery. The clinical notes (from the out of hours service provider) said a possible FRONTLINE PLUS reaction - dyspnoea, collapse and weakness - but they discharged the animal home with the animal owners to keep an eye on her. The following day on 17 MAY 2019 the animal owner reported to the vet that on returning home from the out of hours service, the animal had another episode of collapse and had been weak and unresponsive - they also reported that the animal was lethargic and unresponsive and they were not happy with her. The animal owners brought the animal back into the vets and she was not in a good way at all. The vets started to try and stabilise the cat, she had a low temperature (34), circulation was poor and the animal was generally very weak. They were unable to take blood tests as the animal had pain
sensation and withdrawal but was generally quite flat. After thirty minutes of IVFT at 2.5 times maintenance and warming with a heat mat (temperature 35.2) and hot hounds, blood tests were successfully taken. All renal parameters were markedly elevated and there were also signs of infection - the animal had high White Blood Cell counts. Results were as follows; RBC high -14.30 (6.54-12.2 x10^12/L), HGB high - 18.6 (9.8-16.2 %), RDW high - 31.0 (15-27 %), Glucose high - 9.98 (3.95-8.84 mmol/L), Urea high - 23.6 (5.7-12.9 mmol/L), Phosphate high 3.14 (1-2.42 mmol/L), ALKP low- less than 10 (14-111 U/L) and Potassium high - 6.6 (3.5-5.8 mmol/L). The animal had really poor prognosis, but the animal owners decided that they wanted to see if the animal would respond to treatment and so IVFT was continued and antibiotics - Synulox via SC injection. The animal then started fitting - the animal started vocalising and then had a full seizure followed by collapse and dyspnoea. The animal was given 0.3 ml Diazepam via IV injection. The animal owners requested euthanasia. At that point, the daughter of the animal owner said with hindsight that the cat had been polydipsic at home and the vet discussed that it was most likely a coincidence that this had occurred at the same time as the FRONTLINE PLUS application and that actually the animal had been poorly for a while. The vet thought that it was a mixture of infection, chronic renal failure and the fitting. The attending vet's suspicion of the product being responsible was low.

Demographic information: Age: 12.17 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 2 Hour(s) *	

Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Oxygen and fluids	List signs/symptoms/adverse effects Convulsion Renal insufficiency Death Vocalisation Loss of consciousness Dyspnoea Lethargy Loss of consciousness Hypothermia Peripheral vascular disorder Polydipsia Leucocytosis NOS Increased blood urea nitrogen (BUN) or creatinine Other abnormal test result NOS *See continuation page*	If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 animal Expose duration: 0 Day(s) Patient weight: 3.03 kg		
Human severity category D-A		

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19UK001584

* approximate

Version : unapproved

Page 3. List signs/symptoms/adverse effects - continued

Hyperglycaemia

Increased blood urea nitrogen (BUN) or creatinine

Hyperphosphataemia

Lethargy

Hyperkalaemia

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Craig Tempest		Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19UK001653
	Address United Kingdom			Address --UNKNOWN--	
	Phone # 01132266714			Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 04-26-2019		Date registrant became aware of incident. 05-24-2019	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) Vm 08327/4133	EPA Registration # (Product 2)		EPA Registration # (Product 3)	
	A.I. (s) FIPRONIL SPOT ON CAT	A.I. (s)		A.I. (s)	
	Product 1 name FRONTLINE SPOT ON CAT	Product 2 name		Product 3 name	
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?	
	Formulation	Formulation		Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use		Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No				
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances			

Version : unapproved

Internal ID # 19UK001653

Brief description of incident circumstances

As reported by the animal owner, an intact female feline aged 19 years (signalment otherwise unknown) was given FRONTLINE SPOT ON CAT (batch and expiry unknown, no further details available) by the animal owner. The animal owner reports that the cat died 3 or 4 weeks ago (estimated 26 APR 2019) from old age.

Demographic information: Age: 19 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms:	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: per Unknown Expose duration: Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19UK001653

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Pam Unknown	Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US017325
	Address SAINT CLAIR SHORES MI 48080 U.S.A		Address --UNKNOWN--	
	Phone # 313-550-8237		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 04-07-2018	Date registrant became aware of incident. 04-04-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-5	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE PLUS DOG 45-88 LBS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US017325

Brief description of incident circumstances

Suspected Adverse Event: On 4 Apr 2019 the pet owner reported the following event for an unknown canine.
Unknown date 2018*: Pet owner applied 1 dose of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) in an unknown manner. At an unknown time following the application, the pet owner stated that the pet died from an unknown medical condition. The general health of the dog is unknown. No further medical information available.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: Unknown - Sex : Unknown Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms:	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per 1 animal Expose duration: Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US017325

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Judy Guaraldo	07-23-2019		19US021004

Address	Address
115 Dunbrdige Dr. PALM HARBOR FL 34684 U.S.A	--UNKNOWN--
Phone # 727-786-3420	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	03-29-2019	04-18-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-5		
A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS DOG 5-22 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Intentional misuse No		See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US021004

Brief description of incident circumstances

Suspected Adverse Event: On 18 Apr 2019, the owner reported the following event for 2 unknown canines Shetland Sheep Dog (Sheltie) (all signalments unknown).
25 Jan 2019: The owner applied an a little less than half of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) to Breezy, 3 year old, 22 pound, pregnant female.
29 Mar 2019: The dog gave birth to a litter. 2 of the puppies from that litter had facial deformities. Both puppies were bloated. The puppies were taken to the emergency clinic and passed away naturally.
The owner reported issues with other litters (see cases 19US021003 and 19US021005).The mother dog also received Interceptor once monthly, on the first of the month, year-round for an unknown number of years. No further medical information expected.
UPDATE 28Jun2019: On further review of case, changed route of administration to unknown.

Demographic information: Age: 0 Day(s) - Sex : Unknown Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 9 Week(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Birth defect Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: partial dose to mother Expose duration: mother treatment Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US021004

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Judy Guaraldo	07-23-2019		19US021005

Address	Address
115 Dunbridge dr. PALM HARBOR FL 34684 U.S.A	--UNKNOWN--
Phone # 727-786-3420	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	04-16-2019	04-18-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-5		
A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS DOG 5-22 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Intentional misuse No		See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US021005

Brief description of incident circumstances

Suspected Adverse Event: On 18 Apr 2019, the owner reported the following event for 3 canines Sheltland Sheep Dog (Sheltie) (all signalments unknown).
25 Jan 2019: The owner applied a little less than a full vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) to Wish, 4.5 year old, 21 pound, pregnant lactating female, Shetland Shepherd (Sheltie)
1 Apr 2019: The owner gave the mother an unknown dose of INTERCEPTOR.
16 Apr 2019: The dog gave birth. 3 of the puppies from that dog's litter had deformities. Their jaws were not formed properly and had severe cleft palates. They were euthanized. The owner reported issues with other litters (see cases 19US021003 and 19US021004). No further medical information expected.
UPDATE 28Jun2019: On further review of case, changed route of administration to unknown.

Demographic information: Age: 0 Day(s) - Sex : Unknown Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 11 Week(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Birth defect Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: partial dose to mother Expose duration: mother treatment Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US021005

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Linda House	Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US024748
	Address 722 Northern Ave GREEN BAY WI 54303 U.S.A		Address --UNKNOWN--	
	Phone # 920-405-0182		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 04-27-2019	Date registrant became aware of incident. 05-06-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-4	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE PLUS CATS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? No Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Between the shoulders (topical	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US024748

Brief description of incident circumstances

Suspected Adverse Event: On 6 May 2019, the owner reported the following event for Blackie, 10 pound, male, mixed Feline (all other signalments unknown).
26 Apr 2019: One vial of FRONTLINE PLUS CATS (S40606AW) was applied between the shoulder blades of a stray cat.
27 Apr 2019: The cat became more vostrous than normal. The pet did not present to the clinic and no treatment was provided.
3 May 2019: The cat passed away.
The cat received the prodcut once before on 1 Oct 2018* with no issue. There is on other cat in the household that received the product and experienced symptoms (see case 19US024733). No further medical information is expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: Unknown - Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Vocalisation Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 10 lbs			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US024748

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Cathy Huggins	07-23-2019	Dr Geofrey LANDAU	19US025059

Address	Address
ALLATOONA ANIMAL HOSPITAL 6733 BELLS FERRY RD WOODSTOCK GA, 30189 U.S.A	ALLATOONA ANIMAL HOSPITAL 6733 BELLS FERRY RD WOODSTOCK GA, 30189 U.S.A
Phone # 678-445-1111	Phone # 678-445-1111

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	02-24-2017	05-07-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
2517-145-65331		
A.I. (s) FIPRONIL 9.8%/ETOFENPROX 15%/S-METHOPRENE 11.8% SQUEEZE-ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE TRITAK FOR CATS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US025059

Brief description of incident circumstances

Suspected Adverse Event: On 7 May 2019 a technician reported the following event for Sunny, a 18 year old spayed female Domestic Shorthair of unknown weight.
8 Apr 2014: Owner purchased 6 doses FRONTLINE TRITAK FOR CATS (2282P12) with unknown application dates.
Unknown date: Cat was diagnosed with kidney disease.
Unknown date: Cat was diagnosed with lymphoma.
24 Feb 2017: Cat was euthanized.
This cat was mentioned in case 19US025000 because that cat was received the TRITAK bought for Sunny. The clinic stated the cat was euthanized due to poor prognosis due to kidney disease and lymphoma. No further medical information expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 18 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 2 Year(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Renal disorder NOS Lymphoma Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US025059

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Brooke Bowen	07-23-2019		19US025234

Address	Address
301 7th st NW FORT PAYNE AL 35967 U.S.A	--UNKNOWN--

Phone #	Phone #
256-996-3326	

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	04-28-2019	05-08-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-4		
A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS CATS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Yes Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19US025234

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 8 May 2019, the pet owner reported the following event for Toby a male neutered, 18 year old, 4 pound, Maine Coon Cat.
8 May 2017*: The pet owner previously applied unknown amount of Revolution to the body of Toby.
27 Apr 2018*: The pet owner first noticed fleas on the body of Toby and jumping on her in the home. The pet owner applied FRONTLINE PLUS CATS (lot number unknown) topically to the body of Toby with 15-20+ fleas present on his body.
21 May 2018: Toby was taking Amoxicillin for urinary tract infection for 2* weeks.
27 Apr 2019: The pet owner applied one dose of FRONTLINE PLUS CATS topically according to the label to body of Toby with 20+ fleas.
28 Apr 2019: The pet owner continued to see 20+ fleas on the body of Toby.
2 May 2019*: Toby was taking unknown amount of iron supplement for anemia.
5 May 2019: The pet owner bathed Toby with Dawn dish soap.
6 May 2019: Toby was presented to veterinarian and was euthanized.
8 May 2019: At time of report, Toby was in fair health at time of application. Toby has no history of skin problems. Toby has had flea problem before but it never resolved. Toby is strictly indoors. The pet owner stated that Toby is both blind and deaf. The home environment has been treated. Toby shared FRONTLINE PLUS CATS with two other cats in the home with no issues. No further information.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 18 Year(s) - Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 12 Month(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Euthanasia	List signs/symptoms/adverse effects Lack of efficacy Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: Patient weight: 4 lbs			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US025234

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Sheri Saumers	07-23-2019		19US025338

Address	Address
11931 Juniette Street CULVER CITY CA 90230 U.S.A	--UNKNOWN--

Phone #	Phone #
310-827-3357	

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	05-01-2019	06-24-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-4		
A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS CATS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	Base of Skull and btw Shoulder	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19US025338

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 8 May 2019, the pet owner reported the following event for Ms Kitty, a 16 year old, 10* pound, Unknown rescue feline.
1 Feb 2019*: Fleas and flea dirt were first noticed.
30 Mar 2019 and 30 Apr 2019: She began receiving her seasonal doses of FRONTLINE PLUS(S40815BW).
1 May 2019*: The owner noticed fleas and flea dirt on the animal still after a full month of use with the product, and has occasionally seen 1 a flea on her after holding the animal. The animal was itching occasionally as well. This is still ongoing as of this day.
The cat has used Frontline seasonally before in 2018*, and the owner stated it worked well.
Briefly covered No further medical information expected.
UPDATE 16 May 2019: Case updated to inquiry due to treatment program not respected
UPDATE 24 Jun 2019: Per the pet owner the cat died on an unknown date and was still covered in fleas. No further details as the owner disconnected the phone call.

Demographic information: Age: 16 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 16 Month(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lack of efficacy Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 16 Month(s) Patient weight: 10 lbs			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US025338

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Kathy Strapon	07-23-2019	Dr PUZIA	19US025704

Address	Address
111 N Huckleberry Lane HAYWARD WI 54843 U.S.A	SEELEY VETERINARY CLINIC 12942 W COUNTY ROAD OO HAYWARD WI, 54843 U.S.A

Phone #	Phone #
715-699-0577	715-634-5996

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	04-24-2019	05-09-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-4		
A.I. (s)	**A.I. (s)**	**A.I. (s)**
FIPRONIL 10%/S METHOPRENE 12% SPOT ON		
Product 1 name	**Product 2 name**	**Product 3 name**
FRONTLINE PLUS CATS		
Exposed to concentrate prior to dilution ?	**Exposed to concentrate prior to dilution ?**	**Exposed to concentrate prior to dilution ?**
Formulation	**Formulation**	**Formulation**

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19US025704

Brief description of incident circumstances

Suspected Adverse Event: On 9 May 2019, a pet owner reported the following event for Moses, an approximately 11 year old, 19 pound, neutered male Domestic Longhair.
21 Apr 2019: The cat received 1 vial of FRONTLINE PLUS FOR CATS (Lot Unknown, packaging unavailable and not recorded by clinic) between the shoulder blades.
24 Apr 2019: The pet owner noticed that the cat was a little lethargic.
25 Apr 2019: The cat did not greet the owner when he came home. When the cat did finally walk to the owner, he was ataxic and could barely lift his head.
26 Apr 2019: The cat was still ataxic and barley able to lift his head and was lethargic. He presented to the clinic. On presentation, patient had ventroflexion of the neck and was in respiratory distress. Radiographs and bloodwork were unremarkable, though electrolytes were not evaluated. Patient was treated with IV fluids, steroid injection, and oxygen cage support. Pet owner declined emergency referral and euthanasia and pet died approximately three hours after presentation. Pet owner declined necropsy.
This cat had been receiving FRONTLINE seasonally from Apr to Oct since 2009* without any adverse events noted. Patient purchased product from clinic annually. Patient was only pet in the household.
No further medical information is expected.

Demographic information: Age: 11 Year(s) - * Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 3 Day(s)	

Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) IV fluids, oxygen, steroid	List signs/symptoms/adverse effects Lethargy Ataxia Electrolyte disorder Behavioural disorder NOS Dyspnoea Death	If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 19 lbs		
Human severity category D-A		

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US025704

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Rosemary Supernault	07-23-2019	Dr ANSTATT	19US025732

Address	Address
28082 US Hwy 54 PRESTON MO 65732 U.S.A	WARSAW VETERINARY CLINIC PC 1061 E 1ST ST WARSAW MO, 65355 U.S.A
Phone # 417-733-2614	Phone # 660-438-7333

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	02-01-2019	05-09-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-3		
A.I. (s) FIPRONIL SPOT ON DOG	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE TOP SPOT DOGS 45-88 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19US025732

Brief description of incident circumstances

Suspected Adverse Event: On 9 May 2019 a pet owner reported the following event for White Cloud, a male Great Pyrenees of unknown other signalment.
Unknown date: The dog started receiving FRONTLINE TOP SPOT DOGS (unsubstantiated) (lot and expiration unknown) on an unknown schedule, 1 tube applied to the skin between the shoulder blades.
Feb 2019* Dog died of an unknown acute illness.
The owner mentioned this dog during reporting case 19US025712, but stated the dog's death was not related to the use of FRONTLINE. The owner said she used FRONTLINE that she bought over the counter on White Cloud, but said it was not FRONTLINE PLUS, so it is not clear which product was being used. No further medical information expected.

Demographic information: Age: Unknown - Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 31 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death Malaise		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US025732

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Alicia Richardson	07-23-2019	Dr Unknown UNKNOWN	19US026928

Address	Address
FORT BRAGG CA 95437 U.S.A	MENDOCINO COAST ANIMAL HOSPITAL 700 N FRANKLIN ST FORT BRAGG CA, 95437 U.S.A
Phone # 540-765-7269	Phone # 707-964-3448

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	05-09-2019	05-15-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-4		
A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS CATS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Yes Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US026928

Brief description of incident circumstances

Suspected Adverse Event: On 15 May 2019, the pet owner reported the following event for Puck a 10 year old 15 pound male neutered Domestic Longhair (Crossbreed).
8 May 2019: The owner applied 1 vial of FRONTLINE PLUS CATS (L41208, OCT 2017) foreign labeled product to the skin between the shoulder blades. It is unknown if this is the first time the product was applied to the cat. It is unknown what country the FRONTLINE was intended for use.
9 May 2019: The cat was lethargic and not animated. The owner went out of town and left the cat at home alone.
15 May 2019: The owner returned home and the cat was deceased. The mouth and paws of the cat were wet like the cat was drooling. Owner is not sure when the cat died.
There is 1 other cat in the home who received the same product and is not exhibiting any signs. The cat did not present to the vet clinic. The cat was not on any other medications and was in good health prior to application. No further medical information available.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 10 Year(s) - Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lethargy Death Hypersalivation		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 15 lbs			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US026928

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Carol Kain		Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US027163
	Address U.S.A			Address --UNKNOWN--	
	Phone # 561-945-6219			Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 05-01-2019		Date registrant became aware of incident. 05-16-2019	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-5		EPA Registration # (Product 2)		EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON		A.I. (s)		A.I. (s)
	Product 1 name FRONTLINE PLUS DOG 45-88 LBS		Product 2 name		Product 3 name
	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?
	Formulation		Formulation		Formulation
Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use		Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No				
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances			

Version : unapproved

Internal ID # 19US027163

Brief description of incident circumstances

Suspected Adverse Event: On 16 May 2019, Animal owner reported the following event for her Airedale canine.
*01 Jan 2018: The dog started monthly FRONTLINE PLUS DOG 45-88 LBS (Lot unknown).
*01 May 2019: The dog passed away for unknown reasons.
The animal owner called to enquire about the expiration date and inadvertently reported the passing of her dog. The animal owner stated it was to hard for her to deal with and declined providing information. All information is approximated for reporting purposes.
No further information expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: Unknown - Sex : Unknown Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 16 Month(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US027163

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Penelope Branning		Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US027825
	Address U.S.A			Address --UNKNOWN--	
	Phone # 661-718-2167			Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 01-01-2019		Date registrant became aware of incident. 05-20-2019	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-5		EPA Registration # (Product 2)		EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON		A.I. (s)		A.I. (s)
	Product 1 name FRONTLINE PLUS DOG 89-132 LBS		Product 2 name		Product 3 name
	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?
	Formulation		Formulation		Formulation
Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use		Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No				
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances			

Version : unapproved

Internal ID # 19US027825

Brief description of incident circumstances

Suspected Adverse Event: On 20 May 2019, Animal owner reported the following event for her unknown female canine.
*01 Jan 2018: Started FRONTLINE PLUS DOG 89-132 LBS (Lot and expiration date unknown)
*Dec 2018: Last dose given.
*01 Jan 2019: The dog passed away for unknown reasons. All additional information was declined by the owner.
No further information expected.

Demographic information: Age: Unknown - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 31 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US027825

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Rita Mazzola	Submission date. 07-23-2019	Contact person (if different than reporter) Dr Unknown BAYER	Internal ID # 19US028099
	Address 801 Salem Ave ELYRIA OH 44035 U.S.A		Address OBERLIN ANIMAL HOSPITAL INC 45840 KIPTON NICKLE PLATE OBERLIN OH, 44074 U.S.A	
	Phone # 440-225-8283		Phone # 440-774-5311	

Incident Status: New If update,include date of original submission	Location and date of incident. 04-10-2019	Date registrant became aware of incident. 05-21-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-5	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE PLUS DOG 5-22 LBS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? No Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Between the shoulders (topical	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US028099

Brief description of incident circumstances

Suspected Adverse Event: On 21 May 2019 the owner reported the following event for Muffin a *7 year old, 19.5 pound, female spayed Shih Tzu mix.
*Apr 2018: The owner applied 1 vial of FRONTLINE PLUS DOG 5-22 LBS (UNKNOWN) to the skin between the shoulder blades for the first time and continued on a seasonal basis from Apr to Dec each year.
7 Apr 2019: The owner applied the first dose of the season and administered 1 tablet of Interceptor Plus. This was the first time dog had ever received Interceptor.
10 Apr 2019: The dog began having diarrhea every hour and started refusing to eat.
11 Apr 2019: The dog continued with diarrhea and refused to eat.
12 Apr 2019: The dog began vomiting white foam constantly.
13 Apr 2019: The dog became wobbly and back legs would give out.
14 Apr 2019: The dog couldn't crawl out from under the bed and started having constant seizures.
15 Apr 2019: The dog was still having severe neurological symptoms and had lost weight. The dog presented to the vet clinic. The clinic ran bloodwork and diagnosed the dog with diabetes and severe neurological deficits. The owner elected to euthanize the dog.
The dog had a long history of drinking lots of water but was healthy prior to the application. On an unknown date a couple weeks prior to starting the FRONTLINE PLUS the dog took a fall and was placed on an unknown muscle relaxer that the owner gave 1 time and discontinued. Owner believes symptoms were the result of administering both products on the same day. No further medical information expected.
UPDATE 23 May 2019: Contacted clinic and was informed that owner did not purchase FRONTLINE PLUS from the clinic as they do not sell it. The attending veterinarian was not available to discuss the case.
UPDATE 24 May 2019: Attending veterinarian reported that Muffin had a history of urinary issues and was placed on an antibioitic and she got better. On 15 Apr 2019 the glucose was 364 and AP and WBC were elevated (actual values not available
at time of report), and owner elected euthanasia due to monetary reasons. The veterinarian has a low level of suspicion that FRONTLINE PLUS or Interceptor was related to Muffin's illness.
UPDATE 12 Jun 2019: After further review reaction stopped was entered in the patient outcome section.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 7 Year(s) - * Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 3 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Diarrhoea Anorexia Emesis Ataxia Musculoskeletal disorder NOS Convulsion Weight loss Diabetes mellitus Neurological disorder NOS Hyperglycaemia Elevated serum alkaline phosphatase (SAP) Leucocytosis NOS Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 19.5 lbs			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US028099

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Paulette Unknown		Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US029454
	Address Unknown U.S.A			Address --UNKNOWN--	
	Phone # 818-992-8606			Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 01-02-2019		Date registrant became aware of incident. 05-28-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-5	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE PLUS DOG 45-88 LBS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US029454

Brief description of incident circumstances

Suspected Adverse Event: On 28 May 2019, the pet owner reported the following event for a male, German Shepherd of further unknown signalment.
Unknown dates: The canine received unknown FRONTLINE (lot unknown) (product unsubstantiated). The volume, route, and location of administration are unknown. An unknown duration following, the canine expired via unknown causes, not provided by the reporter.
A second case was reported for another dog who received FRONTLINE. Please see case 19US029461.
No further medical information expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: Unknown - Sex : Male Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US029454

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Dr COREY	07-23-2019		19US029500

Address	Address
TUCUMCARI ANIMAL HOSPITAL PO BOX 1204 TUCUMCARI NM, 88401 U.S.A	--UNKNOWN--
Phone # 575-461-3900	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	05-24-2019	05-24-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-5		
A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS DOG 5-22 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Intentional misuse No	Unknown	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19US029500

Brief description of incident circumstances

Suspected Adverse Event: On 24 May 2019, the following event was reported to Safety Call International (SCI) by the veterinarian for Ziggy, an 18 pound spayed female Chihuahua of unknown age.
24 May 2019: At approximately 11:00 AM the canine received FRONTLINE PLUS DOG 5-22 LBS (S61006AL) for the first time, unknown dose, route, or application site at the veterinary clinic. At approximately 4:30 PM the pet owner found the canine splayed out on the kitchen floor and had defecated and urinated. Patient had watery stool while on the kitchen floor. The patient presented to the clinic with lethargy, dyspnea, stiffness of the limbs, erythema of both inner ears, and bleeding from the rectum and vulva. The attending veterinarian bathed the patient with an unknown product. The canine expired under unknown circumstances at an unknown time the same date and it is unknown if a necropsy was performed.
No further information is available at this time.

Demographic information: Age: Unknown - Sex : Female Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 0 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Bathed with an unknown	List signs/symptoms/adverse effects Involuntary defecation Urinary incontinence Recumbency Diarrhoea Lethargy Dyspnoea Muscle stiffness Ear canal disorder Rectal haemorrhage Vaginal haemorrhage Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per Unknown Expose duration: 0 Day(s) Patient weight: 18 lbs			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US029500

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Sandra Gallagher	07-23-2019		19US029538

Address	Address
2220 Calle Vista Dr FLORISSANT MO 63031 U.S.A	--UNKNOWN--
Phone # 314-838-9161	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	05-01-2019	05-28-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
2596-178-65331		
A.I. (s) FIPRONIL 9.8% / S-METHOPRENE 8.8% / PYRIPROXYFEN 0.25% TOPICAL SOLUTION	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE GOLD DOG 5-22 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation Topicals	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Intentional misuse No	Unknown use	See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US029538

Brief description of incident circumstances

Suspected Adverse Event: On 28 May 2019, the animal owner reported the following event for a canine of unknown signalment.
Unknown date: The canine received FRONTLINE GOLD DOG 5-22 LBS (lot unknown) unknown volume via an unknown route at an unknown location of the body at an unknown interval for an unknown length of time. It is unknown if the canine exhibited any clinical signs. It is unknown if any diagnostics or treatments were initiated. It is unknown if the canine expired naturally or was humanely euthanised. The remains have been disposed.
This is the extent of information known as the owner refused to report. No further information expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: Unknown - Sex : Unknown Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 0 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per Unknown Expose duration: Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US029538

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Belinda Milton	Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US030302
	Address KISKI VALLEY ANIMAL CLINIC 103 RHODA AVE LEECHBURG PA, 15656 U.S.A		Address --UNKNOWN--	
	Phone # 724-478-4800		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 05-04-2019	Date registrant became aware of incident. 05-30-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-4	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE PLUS CATS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? No Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Between the shoulders (topical	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US030302

Brief description of incident circumstances

Suspected Adverse Event: On 30 May 2019, the clinic reported the following event for Mance, 3 years old, 9 pounds, neutered male, Domestic Shorthair (crossbreed).
1 May 2019*: One vial of FRONTLINE PLUS CATS (540606)(Invalid lot) was applied between the shoulder blades, by the pet owner.
4 May 2019*: The cat had seizure like activity and was walking into walls disoriented.
13 May 2019: The cat presented to clinic. The veterinarian did a comprehensive exam, bloodwork and administered and unknown amount of fluids. Antibiotics were prescribed to the cat.
17 May 2019:The cat presented to clinic again because the pet owner stated it was declining in health. The veterinarian did a pre-anesthetic blood panel and gave an unknown amount of fluids. The clinic stated that those results were showing improvement.
21 May 2019: The pet owner reported to the clinic that the pet was having multiple seizures at home.
23 May 2019: The presented to clinic for having a seizure earlier in the day. The clinic gave an injection of an unknown amount of diazepam. The veterinarian prescribed phenobarbital.
30 May 2019: The cat was euthanised at another clinic.
No further medical information is expected.
UPDATE 4 Jun 2019: As reported by the veterinarian, the cat was in good health at the time FRONTLINE PLUS was applied. The product was obtained from a feed store and the product package was not available. On 13 May 2019, blood work was performed and the cat had elevated renal values. The cat was treated with SC fluids and an unknown antibiotic. The cat improved for 3-4 days but then symptoms returned. The veterinarian's level of suspicion that FRONTLINE PLUS caused the clinical signs is high. No further information is expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 3 Year(s) - Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 3 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) SC fluids, unknown	List signs/symptoms/adverse effects Disorientation Death Increased blood urea nitrogen (BUN) or creatinine Convulsion		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) Expose duration: Patient weight: 9 lbs			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US030302

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Risa Turpine	Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US030456
	Address RIDGELAND MS 39157 U.S.A		Address --UNKNOWN--	
	Phone # 662-736-2220		Phone #	

Incident Status: New If update,include date of original submission	Location and date of incident. 01-01-2013	Date registrant became aware of incident. 05-28-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-4	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE PLUS CATS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? No Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Between the shoulders (topical	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US030456

Brief description of incident circumstances

Suspected Adverse Event: On 28 May 2019, the owner reported the following event for Molly, 18 year old, 9 pound, spayed female, Domestic Longhair feline.
2013*: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades on a seasonal basis. The cat experienced strange behavior like the product burned. There was no visible irritation on the pet. The pet did not present to the clinic and no treatment was provided. The cat recovered after an unknown period of time. The cat passed away on another unknown date.
The pet has received the product since 2001* with the same symptoms. There is 1 other cats and a dog in the household that received the FRONTLINE and experienced symptoms (see case 19US029566, and 19US029456). No further medical information is expected.

Demographic information: Age: 18 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 0 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Behavioural disorder NOS Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: Patient weight: 9 lbs			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US030456

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Dr HINAN	Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US030513
	Address PETVET CARE CENTERS U.S.A		Address --UNKNOWN--	
	Phone # 267-803-4915		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 05-13-2019	Date registrant became aware of incident. 05-31-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-1	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL SPRAY	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE SPRAY	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Yes Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US030513

Brief description of incident circumstances

Suspected Adverse Event: On 31 May 2019, the owner reported the following event for Valentino, 2 year old, 1.97 Kilograms, intact male, Angora Rabbit.
6 May 2019: The rabbit presented to the clinic in poor health. The pet was anorexic, anemic and had a large number of fleas. Approximately 2-3 pumps of FRONTLINE SPRAY (R00901A) were applied over the pet.
13 May 2019: The rabbit began experiencing lethargy and seizures. The duration of the seizure is unknown. They occurred sporadically. The pet presented to the emergency clinic. The attending veterinarian started IV fluid and Metoclopramide. The pet was also treated with Midazolam (0.08mg) after each seizure.
14 May 2019: The pet had a stiff gait upon exam. A PCV was run which came back at 42. A blood chemistry was also run which showed elevated creatinine and BUN. The pet was treated with Keppra.
16 May 2019: The rabbit experienced a seizure, which lead to cardiac arrest. The attending veterinarian administered Epinephrine and attempted CPR. The rabbit passed away.
No further medical information is expected.

Demographic information: Age: 2 Year(s) - Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Week(s)	

Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Metoclopramide, IV	List signs/symptoms/adverse effects Lethargy Musculoskeletal disorder NOS Increased blood urea nitrogen (BUN) or creatinine Cardiac arrest Death Convulsion	If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown Expose duration: 0 Day(s) Patient weight: 1.97 kg		
Human severity category D-A		

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US030513

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Christine Trautman	07-23-2019		19US031015

Address	Address
Reading PA U.S.A	--UNKNOWN--

Phone #	Phone #
610-207-0909	

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	01-01-2017	06-03-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-5		
A.I. (s)	**A.I. (s)**	**A.I. (s)**
FIPRONIL 10%/S METHOPRENE 9% SPOT ON		
Product 1 name	**Product 2 name**	**Product 3 name**
FRONTLINE PLUS DOG 89-132 LBS		
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Intentional misuse No	Unknown use	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19US031015

Brief description of incident circumstances

Suspected Adverse Event: On 03 Jun 2019, the animal owner reported the following event for an unknown canine, a 13 year old*, unknown weight, neutered male German Shepherd Dog.
Unknown date: The canine had FRONTLINE PLUS (unsubstantiated) (lot and expiration unknown) one dose applied topically once down the back for the first time. An unknown time post application the owner noticed he had sores along his back. It is unknown if he presented to the veterinary clinic. It is unknown if any treatments were administered. It is unknown if his symptoms completed resolved.
Jun 2017*: An unknown time post the application, he was humanely euthanized for unknown unrelated issues.
The product was never applied subsequently. He did have a pertinent medical history of atopic dermatitis. This is the extent of information known as the owner refused to complete reporting. No further information expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 13 Year(s) - * Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Application site lesion Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US031015

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Julie Curtis	Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US032641
	Address PO 304 RABUN GAP GA 30568 U.S.A		Address --UNKNOWN--	
	Phone # 706-982-9305		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 01-02-2018	Date registrant became aware of incident. 06-07-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 2596-178-65331	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 9.8% / S-METHOPRENE 8.8% / PYRIPROXYFEN 0.25% TOPICAL SOLUTION	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE GOLD DOG 45-88 LBS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation Topicals	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US032641

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 7 Jun 2019, the animal owner reported the following event for 2* dogs of unknown signalment.
1 Jan 2018*: The patients received a dose of FRONTLINE(Unsubstantiated)(lot and expiration unknown).
2 Jan 2018*: The patient began experiencing seizures and some time later passed away.
Further information is unknown as report declined further query. Owner had called in about a different animal see case 19US032352.
No further medical information expected.
UPDATE 15 Jul 2019: The case was changed to serious and the reportability to 15-Day.

Demographic information: Age: Unknown - Sex : Unknown Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death Convulsion		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per Unknown Expose duration: Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US032641

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Sharon Larando	Submission date. 07-23-2019	Contact person (if different than reporter) Dr Jeff MILBURN	Internal ID # 19US033106
	Address 1 Daniel St GORHAM ME 04038 U.S.A		Address EDGEWOOD ANIMAL HOSPITAL 181 STATE ST GORHAM ME, 04038 U.S.A	
	Phone # unknown		Phone # 207-839-6558	
	Incident Status: New If update,include date of original submission	Location and date of incident. 01-01-2013	Date registrant became aware of incident. 06-10-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-4	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE PLUS CATS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US033106

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 10 Jun 2019 the pet owner reported the following event via mail for Poe, a feline of unknown further signalment.
Unknown date: Started on FRONTLINE PLUS CATS (product unsubstantiated) (lot and expiration unknown), unknown volume, route, application site, and frequency.
Unknown date 2013: The feline was diagnosed with Lyme disease via an unknown test type. It is unknown if the feline was symptomatic at this time or what treatment was performed.
Unknown date 2015: The feline was euthanized under unknown circumstances.
The pet owner reported via mail a second feline has been diagnosed for Lyme disease while on FRONTLINE PLUS CATS (product unsubstantiated) (see case number 19US033122). No further information is available at this time.
UPDATE 17 Jun 2019: Per phone call received from pet owner:
Unknown Date 2013: The cat was lethargic, anorexic, and had trouble standing for approximately 1-2 days. Then the cat presented to the clinic and was diagnosed Lyme and Anaplasma positive via an uknown test. The cat was treated with doxycycline.
The cat continued to lose weight over the next few years and ultimately was euthanized in Jul 2015. No further medical information expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 9 Year(s) - * Sex : Male Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 9 Year(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) doxycycline	List signs/symptoms/adverse effects Lack of efficacy Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Unknown per Unknown Expose duration: Unknown duration Patient weight: 6 lbs			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US033106

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Jenifer Angelina	07-23-2019	unknown	19US034131

Address	Address
Po Box 431 PEGRAM TN 37143 U.S.A	ALL ANIMALS VET HOSPITAL PLLC 2161 HIGHWAY 48 N DICKSON TN, 37055 U.S.A
Phone # 615-491-6734	Phone # 615-446-7991

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	06-05-2019	06-13-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-4		
A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS CATS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Yes Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US034131

Brief description of incident circumstances

Suspected Adverse Event/Lack of efficacy: On 13 Jun 2019, the owner reported the following event for Beth, 1 year old, 6.1 pound, female neutered, Domestic Shorthair.
5 June 2019: One vial FRONTLINE PLUS CATS (S40603AW) was applied topically in between the shoulder blades in one location.
Within 24 hours the cat became extremely lethargic and in extreme pain when touched or palpated. The pet was presented to the emergency clinic. A CBC/CHEM was performed and the cat was diagnosed with Bobcat Fever from a tick bite. It is unknown what treatment the cat was given.
9 Jun 2019: The cat was euthanized.
This cat has been on FRONTLINE PLUS CATS off and on since 2018.There are 2 other cats within the home using the product and did not experience any adverse events. No further medical information expected at this time.
UPDATE 2 Jul 2019 per medical records received on 18 Jun 2019:
5 June 2019: The pet presented to the clinic for having a tick on the medial canthus of her right eye, weight loss, not eating or drinking, fever that began on 4 Jun 2019, laying around, and limping on her left rear leg. The pet's temperature was 104.7 F. Blood work revealed the following abnormalities: HCT decreased 27.8%, Hb decreased 93, decreased reticulocytes/Hb 12.5, decreased WBC 2.34, decreased neutrophils 1.63, bands suspected, decreased lymphocytes 0.48, decreased eosinophils 0.03, decreased platelets 17; increased glucose 221, increased total bilirubin 4.3, and decreased alkaline phosphatase less than 10. No platelets were noted on a blood smear; ghost red blood cells were noted, as well as significantly decreased WBC. The veterinarian suspected cytauxzoon felis. The pet was treated with dexamethasone, Convenia, and SC fluids.
6 Jun 2019: Piroplasms were observed on a new blood smear confirming the diagnosis of cytauxzoon felis. No further medical information expected.

Demographic information: Age: 1 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 0 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) dexamethasone, Convenia,	List signs/symptoms/adverse effects Lethargy General pain Death Lack of efficacy Weight loss Anorexia Adipsia Hyperthermia Anaemia NOS Decreased percentage of reticulocytes Leucopenia Neutropenia Lymphopenia Thrombocytopenia Blood and lymphatic system disorder NOS *See continuation page*		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 6.1 lbs			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US034131

Version : unapproved

Page 3. List signs/symptoms/adverse effects - continued

Hyperglycaemia

Elevated total bilirubin

Low serum alkaline phosphatase (SAP)

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Tanya Parrish	07-23-2019		19US034918

Address	Address
5818 SW 91st Place Lake Butler FL 32054 U.S.A	--UNKNOWN--
Phone # 386-288-4154	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	06-01-2019	06-17-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-5		
A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS DOG 5-22 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
Intentional misuse No	Unknown use	See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US034918

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 14 Jun 2019, the pet owner reported to SafetyCall International (SCI) the following event for Logan, a 3 year old*, 6 pound, intact male Shih Tzu.
Unknown date, years ago: The dog began receiving FRONTLINE PLUS FOR DOGS (unsubstantiated) (lot unknown) monthly with unknown purchase history. It is unknown how the product was applied.
Mar 2019* through May 2019*: The owner has continued to notice fleas. The dog's excursion history is unknown. The pet owner states that she has bathed the dog monthly with a mixture of baby shampoo and dish soap to help kill the fleas.
Unknown date: The dog presented to the veterinary clinic. The dog was diagnosed with anemia, secondary to persistent fleas. It is unknown what other diagnostics were performed or if treatments were provided. The veterinarian had advised a transfusion, but that could not be pursued.
1 Jun 2019*: The dog passed away.
There a total of 4 canines and 1 felines in the report, but it is unknown how many animals are in the household. See related cases 19US034915, 19US035690, 19US035694, 19US035695, and 19US035698. No further medical information expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 3 Year(s) - * Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 3 Month(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lack of efficacy Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 8 Week(s) 5 Day(s) Patient weight: 6 lbs			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US034918

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Joan Unknown		Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US036407
	Address U.S.A			Address --UNKNOWN--	
	Phone # 718-296-3840			Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 02-01-2016		Date registrant became aware of incident. 06-24-2019	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-5		EPA Registration # (Product 2)		EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON		A.I. (s)		A.I. (s)
	Product 1 name FRONTLINE PLUS DOG 0-22 LBS		Product 2 name		Product 3 name
	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?
	Formulation		Formulation		Formulation
Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use		Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No				
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances			

Version : unapproved

Internal ID # 19US036407

Brief description of incident circumstances

Suspected Adverse Event: On 24 Jun 2019, animal owner inquired about expiration dates and reported the following event for her dog. All signalment is unknown.
*Jan 2016: The dog received FRONTLINE PLUS DOG 0-22 LBS (lot unknown). The product is unsubstantiated.
*Feb 2016: The dog passed away for unknown reasons.
All additional inforamtion is unknown. No further information expected.
UPDATE 3 JUL 2019: Upon internal review, corrected Outcomes on Event narrative screen to Death and REaction stopped.

Demographic information: Age: Unknown - Sex : Unknown Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 31 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US036407

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Beverly UNKNOWN	07-23-2019	Dr Stein SMITH	19US036933

Address	Address
118 NW Sunset Way WALDPORT OR 97394 U.S.A	ANIMAL MEDICAL CARE OF NEWPORT PC 162 NE 10TH ST NEWPORT OR, 97365 U.S.A
Phone # 541-272-4913	Phone # 541-265-6672

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	06-10-2019	06-25-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-5		
A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS DOG 5-22 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US036933

Brief description of incident circumstances

Suspected Adverse Event: On 25 Jun 2019 a pet owner's mother reported the following event for Tiny, 5 pound*, 11 year old, female spayed Pomeranian.
9 Jun 2019*: Owner applied FRONTLINE PLUS DOG 5-22 LBS (S61017) to the skin between Tiny's shoulder blades for the first time.
10 Jun 2019*: Dog became slightly lethargic.
11 Jun 2019*: Pet owner washed the dog in Dawn dish soap.
13 Jun 2019*: Dog got a drink, laid down by her water bowl, and died.
The dog had no known health problems and did not receive continuous medications including heartworm preventative. The owner also reported the second dog in the home died after receiving the product: 19US036945. No further information at this time.
UPDATE 26 June 2019: Veterinarian reports dogs have not been to his clinic for medical care since Nov 2016. One of the bodies the owner brought in had maggots and bodies were in a state of decomposition preventing any hopes of a necropsy.

Demographic information: Age: 11 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lethargy Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 5 lbs*			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US036933

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Beverly UNKNOWN	07-23-2019	Dr Stein SMITH	19US036945

Address	Address
118 NW Sunset Way WALDPORT OR 97394 U.S.A	ANIMAL MEDICAL CARE OF NEWPORT PC 162 NE 10TH ST NEWPORT OR, 97365 U.S.A
Phone # 541-272-4913	Phone # 541-265-6672

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	06-17-2019	06-25-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-5		
A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS DOG 5-22 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US036945

Brief description of incident circumstances

Suspected Adverse Event: On 25 Jun 2019 a pet owner's mother reported the following event for Bear, a 5 pound*, 10 year old, intact male Pomeranian/Wolf hybrid.
16 Jun 2019*: Owner applied FRONTLINE PLUS DOG 5-22 LBS (S61017) to the skin between Bear's shoulder blades for the first time.
17 Jun 2019*: Pet owner washed the dog in Dawn dish soap. Owner reported during bath something brown came off the dog which she does not believe is dissolved flea feces because she has seen that before.
18 Jun 2019*: Dog started coughing.
20 Jun 2019*: Dog was laying on his bed and was dead.
The dog had no known health problems and did not receive continuous medications including heartworm preventative. The dog's body has been on the garage floor since he died. No further information at this time.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 10 Year(s) - Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Hair change Cough Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 5 lbs*			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US036945

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Ken Smith		Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US037279
	Address TN U.S.A			Address --UNKNOWN--	
	Phone # 731-610-6465			Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 05-10-2019		Date registrant became aware of incident. 06-26-2019	Was incident part of larger study ? No
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-4		EPA Registration # (Product 2)		EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON		A.I. (s)		A.I. (s)
	Product 1 name FRONTLINE PLUS CATS		Product 2 name		Product 3 name
	Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?		Exposed to concentrate prior to dilution ?
	Formulation		Formulation		Formulation
Row 3 Incident Circumstances	Evidence label directions were not followed? No Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Between the shoulders (topical		Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes	
	Applicator certified PCO? No				
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances			

Version : unapproved

Internal ID # 19US037279

Brief description of incident circumstances

Suspected Adverse Event: On 26 Jun 2019, the pet owner reported the following event for a feline with unknown signalment.
30 Apr 2019*: The cat began receiving FRONTLINE PLUS CATS (S40717AW) for the first time this year. The pet owner cannot remember if he has used this product previously or another topical flea prevention.
10 May 2019: The cat began experiencing seizures. The cat would go stiff, fall over, and twitch. The duration is unknown.
11 May 2019: The cat continued experiencing seizures. The cat would go stiff, fall over, and twitch. The cat bit itself and urinated on itself during these events. The duration is unknown.
12 May 2019: The cat passed away.
The cat had not presented to the veterinary clinic.
Another cat in the home also passed away recently, see case 19US037764. Two other cats also experienced seizures, see 19US037766 and 19US037767. The pet owner also reported that he was still seeing fleas, see case 19US037768. No further medical information expected.

Demographic information: Age: Unknown - Sex : Unknown Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 10 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Convulsion Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US037279

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Ken Smith		Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US037764
	Address TN U.S.A			Address --UNKNOWN--	
	Phone # 731-610-6465			Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 05-17-2019		Date registrant became aware of incident. 06-26-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-4	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE PLUS CATS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Between the shoulders (topical	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US037764

Brief description of incident circumstances

Suspected Adverse Event: On 26 Jun 2019, the pet owner reported the following event for a feline with unknown signalment.
30 Apr 2019*: The cat received FRONTLINE PLUS CATS (S40717AW) for the first time this year. Fleas were seen prior to product application. The pet owner cannot remember if he has used this product previously or another topical flea prevention.
17 May 2019: The cat began experiencing seizures. The cat would go stiff, fall over, and twitch. The duration is unknown.
18 May 2019: The cat continued experiencing seizures. The cat would go stiff, fall over, and twitch. The duration is unknown. The cat passed away.
The cat had not presented to the veterinary clinic.
There were a total of 15 cats in the home. Another cat in the home also passed away recently, see case 19US037279. Two other cats also experienced seizures, see 19US037766 and 19US037767. The pet owner also reported that he was still seeing fleas, see case 19US037768. No further medical information expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: Unknown - Sex : Unknown Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 17 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Convulsion Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US037764

* approximate

Version : unapproved

BICHON FRISE CASES

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Elizabeth Bunyan	07-23-2019		19UK001301

Address	Address
LU1 4HZ United Kingdom	--UNKNOWN--

Phone #	Phone #
07985421284	

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	02-16-2019	04-16-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
Vm 08327/4270		
A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS SPOT ON DOGS S	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	Unknown use	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19UK001301

Brief description of incident circumstances

As reported by the animal owner, Billy, a 5.2 year old male neutered Bichon Frise canine, weighing 9 kg and in good condition, was administered FRONTLINE PLUS SPOT ON DOG S (batch RS1906AL expiry 02 AUG 2020) topically by the animal owner at a dose of 1 dosage form on 16 FEB 2019 as they saw fleas. The animal owner bought the product and was advised by the SQP that the product was a repellent. The animal owner reports that they are still seeing fleas 3 months. They have also used a household spray and they followed all the instructions as per the can. The animal owner reports that the product is not working.

Demographic information: Age: 5.2 Year(s) - Sex : Male Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 0 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lack of efficacy		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 dosage form per 1 animal Expose duration: 0 Day(s) Patient weight: 9 kg			
Human severity category D-D			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19UK001301

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Beverly Unknown	07-23-2019		19US018306

Address	Address
JOHNS ISLAND SC 29455 U.S.A	--UNKNOWN--
Phone # 248-892-377	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	04-02-2019	04-09-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-5		
A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS DOG 5-22 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US018306

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 9 Apr 2019, the pet owner reported the following event for Chloe, 12 year old, 16 pound, female spayed, Bichon Frise.
2 Apr 2019*: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (F6106AL) was applied to the dog in one area between the shoulder blades. The owner has been seeing a large amount of fleas on the dog every day since application.
8 Apr 2019: The dog was bathed in dawn dish soap.
The dog goes out for potty breaks and recreation on the island where they are visiting. There is a lot of vegetation and sand, urban wildlife possible. There are no fleas seen in the home, but the owner is having the home exterminated just in case. The dog has a history of skin issues, was given an unknown steroid injection at an unknown date for itchy skin. Owner treats year round with FRONTLINE. No further information available.

Demographic information: Age: 12 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 3 Year(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lack of efficacy		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 3 Year(s) 2 Month(s) Patient weight: 16 lbs			
Human severity category D-D			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US018306

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Maryanne Unknown	07-23-2019		19US023558

Address	Address
DIAMOND BAR CA 91765 U.S.A	--UNKNOWN--

Phone #	Phone #
909-860-3576	

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	04-30-2019	05-01-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-5		
A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS DOG 5-22 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19US023558

Brief description of incident circumstances

Suspected Lack of Efficacy: On 1 May 2019, the pet owner reported the following event for Christy, 11 pound, female spayed, Bichon Frise. All other signalments unknown.
26 Apr 2019: The dog was bathed by the groomer in an unknown shampoo.
29 Apr 2019: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S60714AX) was applied to the dog in one area between the should blades.
30 Apr 2019: The owner saw 1-2 fleas on the dog and removed them. The owner has not seen any more fleas on the dog since she removed them.
The owner has been treating the dog year round with FRONTLINE PLUS for an unknown number of years. The dog goes out for potty breaks and recreation in yard where urban wildlife present. There a no fleas present in the home. The dog has no history of skin issues. There is one other dog in the home, unknown if it is having an issue with fleas. Owner declined to provide signalments. No further medical information is expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: Unknown - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 3 Month(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Fleas removed.	List signs/symptoms/adverse effects Lack of efficacy		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 3 Month(s) 4 Week(s) Patient weight: 11 lbs			
Human severity category D-D			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US023558

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Caroline Unknown	07-23-2019		19US025507

Address	Address
CITRUS HEIGHTS CA 95610 U.S.A	--UNKNOWN--
Phone # 916-521-6556	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	04-01-2019	05-08-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
65331-5		
A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE PLUS DOG 5-22 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US025507

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 8 May 2019, the owner reported the following event for a 14 pound Bichon Frise.
*1 April 2019: The dog had fleas and one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was topically applied to the skin between the shoulder blades.
1 May 2019: The dog continued to have fleas and one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was topically applied to the skin between the shoulder blades.
8 May 2019: The dog was bathed with whitening shampoo.
The dog is picking up a small quantity of fleas each day and has been each day since April. The dog is treated with FL monthly year round and there aren't any fleas in the home. The dog has access to bark and yard daily. The dog doesn't suffer from any skin issues. There is one other treated dog and 3 treated cats who don't have fleas. No further information available.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: Unknown - Sex : Unknown Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 0 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) whitening shampoo	List signs/symptoms/adverse effects Lack of efficacy		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 12 Month(s) Patient weight: 14 lbs			
Human severity category D-D			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US025507

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Veronica Rohm		Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US031675
	Address 1620 Buckland Ave FREMONT OH 43420 U.S.A			Address --UNKNOWN--	
	Phone # 419-307-8725			Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 03-03-2019		Date registrant became aware of incident. 06-05-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-5	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE PLUS DOG 23-44 LBS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? No Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Between the shoulders (topical	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US031675

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 05 Jun 2019, the animal owner reported the following event for one canine, unknown age, 23.0 pound, unknown sex, unknown reproductive status, Bichon Frise Mix.
02 Mar 2019, 02 Apr 2019, 02 May 2019, and 02 Jun 2019: The canine received FRONTLINE PLUS DOG 23-44 LBS (H65002AL) one dose topically per animal in between the shoulders.
03 Mar 2019: The owner noticed a moderate amount of fleas. The dog frequent the yard which has tall grass. The owner noticed fleas on all of the pets prior to application. The owner is not seeing fleas off of the pets. They have not presented to veterinary clinic. The owner has been treating by bathing all of the animals in the household in Dawn dish soap every two weeks.

There are four felines in the household receiving FRONTLINE PLUS CAT (see case 19US031666) and two canines in the household receiving FRONTLINE PLUS DOG 89-132 LBS (see case 19US031677). No further medical information expected.

Demographic information: Age: Unknown - Sex : Unknown Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 1 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Dawn dish soap	List signs/symptoms/adverse effects Lack of efficacy		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 3 Month(s) Patient weight: 23.0 lbs			
Human severity category D-D			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
19US031675

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Lori unknown	07-23-2019		19US033381

Address	Address
SOUTHVIEW ANIMAL HOSPITAL PA 32 MENDOTA RD INVER GROVE HEIGHTS MN, 55077 U.S.A	--UNKNOWN--
Phone # 651-451-7119	Phone #

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	05-28-2019	06-11-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
2596-178-65331		
A.I. (s) FIPRONIL 9.8% / S-METHOPRENE 8.8% / PYRIPROXYFEN 0.25% TOPICAL SOLUTION	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE GOLD DOG 5-22 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation Topicals	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	down back	See Incident Description Notes
Applicator certified PCO? No		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US033381

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: 11 Jun 2019: A receptionist reported the following event in Molly; a 7 year old, 15.3 pound, spayed, female, Bichon Frise.
01 Jan 2016*: The owner started applying one vial of FRONTLINE GOLD DOGS 5-22 LBS (lot unknown, package unavailable) topically down the back monthly.
28 May 2019: On a routine Idexx 4Dx test the dog was positive for Anaplasmosis. No further medical information expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 7 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 27 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lack of efficacy		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 15.3 lbs			
Human severity category D-C			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US033381

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data

Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID #
Jefferey Leard	07-23-2019	Terry Unknown	19US035630

Address	Address
COASTAL VETERINARY CLINIC 21 BUCK ISLAND RD BLUFFTON SC, 29910 U.S.A	COASTAL VETERINARY CLINIC 21 BUCK ISLAND RD BLUFFTON SC, 29910 U.S.A
Phone # 843-757-1112	Phone # 843-757-1112

Incident Status:	Location and date of incident.	Date registrant became aware of incident.	Was incident part of larger study ?
New If update,include date of original submission	06-07-2019	06-19-2019	No

Row 2 Pesticide(s) Involved

EPA Registration # (Product 1)	EPA Registration # (Product 2)	EPA Registration # (Product 3)
2596-178-65331		
A.I. (s) FIPRONIL 9.8% / S-METHOPRENE 8.8% / PYRIPROXYFEN 0.25% TOPICAL SOLUTION	A.I. (s)	A.I. (s)
Product 1 name FRONTLINE GOLD DOG 5-22 LBS	Product 2 name	Product 3 name
Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
Formulation Topicals	Formulation	Formulation

Row 3 Incident Circumstances

Evidence label directions were not followed?	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).
No Intentional misuse No	Between the shoulders (topical	See Incident Description Notes
Applicator certified PCO? No		

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).	Brief description of incident circumstances
See Incident Description	

Version : unapproved

Internal ID # 19US035630

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 21 Jun 2019 the BI sales representative reported the following event for Annie, a 9 year old (born 19 Nov 2019), 16 pound, spayed female Bichon Frise.
1 Jan 2019*: Started on FRONTLINE GOLD DOG 5-22 LBS (lot number unknown),1 vial, topically between the shoulder blades
1 Jun 2019: The most recent dose was applied. There were no fleas seen at the time of application.
7 Jun 2019: The pet owner began seeing a moderate amount of fleas on the canine. It is unknown if fleas were seen inside the home.
Currently, the pet owner is still seeing fleas on the canine, it is unknown where the canine spends the majority of the time, what areas outside she has access to, or if she has received treatment. There is one other canine in the household that is not exhibiting fleas. No further information is known at this time.

ED_005739D_00014404-00748

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Demographic information: Age: 9 Year(s) - Sex : Female Occupation (if relevant)	Exposure route: Topical / Cutaneous	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 5 Month(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lack of efficacy		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: Patient weight: 16 lbs			
Human severity category D-D			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

19US035630

* approximate

Version : unapproved

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.

Row 1 Administrative Data	Reporter Name Joan Unknown	Submission date. 07-23-2019	Contact person (if different than reporter)	Internal ID # 19US036407
	Address U.S.A		Address --UNKNOWN--	
	Phone # 718-296-3840		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 02-01-2016	Date registrant became aware of incident. 06-24-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-5	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE PLUS DOG 0-22 LBS	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? Intentional misuse No	Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use	Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes
	Applicator certified PCO? No		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description	Brief description of incident circumstances	

Version : unapproved

Internal ID # 19US036407

Brief description of incident circumstances

Suspected Adverse Event: On 24 Jun 2019, animal owner inquired about expiration dates and reported the following event for her dog. All signalment is unknown.
*Jan 2016: The dog received FRONTLINE PLUS DOG 0-22 LBS (lot unknown). The product is unsubstantiated.
*Feb 2016: The dog passed away for unknown reasons.
All additional inforamtion is unknown. No further information expected.
UPDATE 3 JUL 2019: Upon internal review, corrected Outcomes on Event narrative screen to Death and REaction stopped.

Demographic information: Age: Unknown - Sex : Unknown Occupation (if relevant)	Exposure route: unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify) ?
If female, pregnant ?	Was exposure occupational? If yes, days lost due to illness:	Time between exposure and onset of symptoms: 31 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: Unknown			
Human severity category D-A			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

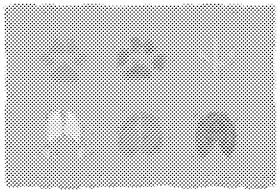
Internal ID #
19US036407

* approximate

Version : unapproved

CERTIFECT CASES

EPA Quarterly Aggregate Report



Number of Incidents and Adverse Effects Reported by Exposure Type and Severity Category (USA)
Reporting Period: 01-Apr-2019 to 01-Jul-2019 [1]
Product Family: CERTIFECT (incl. 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 9.8%/S-METHOPRENE 8.8%/ AMITRAZ 22.1% SPOT-ON / 65331-7	1	0	0	0	0	1
Totals	**1**	**0**	**0**	**0**	**0**	**1**

1. Due to system limitations, the end date is displayed as the first day of the current quarter, however only cases with a date first valid in the evaluated quarter are displayed.

In accordance with global BI policy, legal requirements, and regulations, BI records all adverse events (AE). Collection of an AE report does not constitute an admission by BI that our 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.

Use in Off-Label Species (USA)
Reporting Period: 01-Apr-2019 to 01-Jul-2019 [1]
Product Family: CERTIFECT (incl. 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
No matching records.				

1. Due to system limitations, the end date is displayed as the first day of the current quarter, however only cases with a date first valid in the evaluated quarter are displayed.

USA off-Label species totals are included

In accordance with global BI policy, legal requirements, and regulations, BI records all adverse events (AE). Collection of an AE report does not constitute an admission by BI that our 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.

Number of Incidents and Adverse Effects Reported by Exposure Type and Severity Category (Extraterritorial)
Reporting Period: 01-Apr-2019 to 01-Jul-2019 1
Product Family: CERTIFECT (incl. 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
No matching records.						

1. Due to system limitations, the end date is displayed as the first day of the current quarter, however only cases with a date first valid in the evaluated quarter are displayed.

In accordance with global BI policy, legal requirements, and regulations, BI records all adverse events (AE). Collection of an AE report does not constitute an admission by BI that our 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.

Use in Off-Label Species (Extraterritorial)
Reporting Period: 01-Apr-2019 to 01-Jul-2019 [1]
Product Family: CERTIFECT (incl. 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

No matching records.

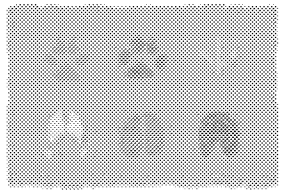
1. Due to system limitations, the end date is displayed as the first day of the current quarter, however only cases with a date first valid in the evaluated quarter are displayed.

Extraterritorial off-label species totals are incldued

In accordance with global BI policy, legal requirements, and regulations, BI records all adverse events (AE). Collection of an AE report does not constitute an admission by BI that our 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.

Confidential - Property of Boehringer Ingelheim Animal Health USA Inc. - Distribute and Disclose Only On a Need To Know Basis

EPA Report



Worldwide Adverse Event Reports Involving - Animal Cases
Reporting Period: 01-Apr-2019 to 01-Jul-2019 [1]

Date case Received	Case type; Case Reference; 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-Apr-2019	UAE; 19US019004; PA; U.S.A	**Species:** Canine **Breed:** Boxer **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 70 lbs	1	1	0	**Product used:** FIPRONIL 9.8%/S-METHO PRENE 8.8%/ AMITRAZ 22.1% SPOT-ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	07-Mar-2019*	07-Apr-2019	0 Day(s)	D-D	Suspected Adverse Event: On 10 Apr 2019, the following event was reported to Safety Call International (SCI) by the pet owner for Anku, a 2 year old, 70 lb neutered male Boxer. 7 Apr 2019: The pet owner applied a dose of CERTIFECT FOR DOGS 45-88 LBS (G90503) to the dog. That evening, the dog became lethargic. 8 Apr 2019: Signs resolved within 12 hours without treatment. The dog has received the product once before on an unknown date without issue. The pet owner also experienced symptoms, 19US018540. No further medical information expected.

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

1. Due to system limitations, the end date is displayed as the first day of the current quarter, however only cases with a date first valid in the evaluated quarter are displayed.

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)
* indicates Approximate date or weight

In accordance with global BI policy, legal requirements, and regulations, BI records all adverse events (AE). Collection of an AE report does not constitute an admission by BI that our 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.

Worldwide Adverse Event Reports - Human Cases

Reporting Period: 01-Apr-2019 to 01-Jul-2019 [1]

Date case Received	Case type; Case Reference; 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 matching records.

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

1. Due to system limitations, the end date is displayed as the first day of the current quarter, however only cases with a date first valid in the evaluated quarter are displayed.

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)
* indicates Approximate date or weight

In accordance with global BI policy, legal requirements, and regulations, BI records all adverse events (AE). Collection of an AE report does not constitute an admission by BI that our 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.

McAlister,Leann (AH RA_PV) BIAH-US-D

From: TrackingUpdates@fedex.com
Sent: Friday, August 30, 2019 9:19 AM
To: McAlister,Leann (AH RA_PV) BIAH-US-D
Subject: FedEx Shipment 776111864165 Delivered

Your package has been delivered

Tracking # 776111864165

Ship date:
Thu, 8/29/2019

LeAnn McAlister
BI AH USA
Duluth, GA 30096
US

Delivered

Delivery date:
Fri, 8/30/2019 9:15 am

Document Processing Desk 6(a)(2)
US EPA - Office of Pesticide Prog
2777 S Crystal Drive
One Potomac Yard - Rm S-4900
ARLINGTON, VA 22202
US

Shipment Facts

Our records indicate that the following package has been delivered.

Tracking number:	776111864165
Status:	Delivered: 08/30/2019 09:15 AM Signed for By: M.MICK
Department number:	0
Invoice number:	0
Purchase order number:	63005
Reference:	402415
Signed for by:	M.MICK
Delivery location:	ARLINGTON, VA
Delivered to:	Receptionist/Front Desk
Service type:	FedEx Standard

	Overnight®
Packaging type:	FedEx® Box
Number of pieces:	1
Weight:	12.00 lb.
Special handling/Services:	Deliver Weekday
Standard transit:	8/30/2019 by 3:00 pm

Please do not respond to this message. This email was sent from an unattended mailbox. This report was generated at approximately 8:18 AM CDT on 08/30/2019.

All weights are estimated.

To track the latest status of your shipment, click on the tracking number above.

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Thank you for your business.

From: helpdesk@epacdx.net
To: McAlister,Leann (AH GI RA PV) BIAH-US-D
Subject: CDX PSP Package Transmitted to OPP
Date: Thursday, March 25, 2021 5:59:59 PM

CAUTION! Please do not click links or open attachments unless you recognize the sender, this email is from an **External Sender** (outside Boehringer-Ingelheim)

Your PSP package (20210325_Resubmission_CoverLetter_EPAAggregateReport2Q19) for BOEHRINGER INGELHEIM ANIMAL HEALTH USA INC. (65331) has been successfully transmitted to OPP.

Below are the application(s) included in this package and their tracking number(s):
Sec3-6(a)(2)-000001: CDX_2021_003368
Sec3-6(a)(2)-000002: CDX_2021_003369
Sec3-6(a)(2)-000003: CDX_2021_003370
Sec3-6(a)(2)-000004: CDX_2021_003371
Sec3-6(a)(2)-000005: CDX_2021_003372
Sec3-6(a)(2)-000006: CDX_2021_003373

Company Name: BOEHRINGER INGELHEIM ANIMAL HEALTH USA INC.
Company Number: 65331

If you have questions concerning this message, you may contact the CDX Help Desk by email at helpdesk@epacdx.net or by calling the CDX Technical Support Staff through our toll free telephone support on (888) 890-1995 between Monday through Friday from 8:00 am to 6:00 pm EST/EDT. For International callers, the CDX Help Desk can also be reached at (970) 494-5500.

CDX Homepage
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