Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
23-Sep-2019	UAE; 19US056631; -; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Capstar; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	20-Sep-2019	23-Sep-2019	3 Day(s)	D-D	Suspected Adverse Event: On 23 Sep 2019 the owner called in the following event for 3 Yorkshire Terriers of unknown signalment. 13 Sep 2019: The owner gave the dogs Capstar. 20 Sep 2019: The owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS (S62106AL) topically between the shoulders of all three dogs for the first time. 23 Sep 2019: The owner noticed that the dogs are pruritic. The owner does not see fleas on the dogs or in the home. The medical history and previous reaction history of the dogs is unknown. No further medical information is expected.
23-Sep-2019	UAE; 19US056637; WI; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Month(s) **Weight:** 3.5 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?:** Unknown to Company	01-Sep-2019*	03-Sep-2019*	2 Day(s)	D-A	Suspected Adverse Event: On 23 Sep 2019, the pet owner reported the following event for a feline, 3.5 pound*, 6 month old*, spayed female. All other signalment is unknown. 1 Sep 2019*: One vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) was applied. It is unknown how the product was applied. 3 Sep 2019*: The cat did not want to eat or drink. The cat did not present to the clinic and no treatment was provided. 4 Sep 2019*: The cat passed. There are 28 other cats in the household that received the product with no symptoms. There is one other cat that also experienced symptoms (see case 19US056615). The owner also reported a quality issue with the product (see case 19US056646). No further medical information expected.
23-Sep-2019	UAE; 19US056663; GA; U.S.A	**Species:** Canine **Breed:** Lhasa Apso **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 43 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical and Opthalmic **Was the product used ok?:** Yes	07-Aug-2019	09-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, a pet owner reported the following event for Dakota, a 14 year old, 43 pound, neutered male Lhasa Apso. 7 Aug 2019: The dog received 1 application of FRONTLINE PLUS DOG 23-44 LBS (S61727AL) topically between the shoulder blades in one spot for the first time. The dog was scratching prior to the FRONTLINE but the owner was not seeing fleas. 9 Aug 2019*: The dog was scratching and the owner felt that it was more than before. 7 Sep 2019: The dog received another application of FRONTLINE. 23 Sep 2019: The dog went to the groomer and she found an unknown amount of live fleas on the dog. The dog was given Bravecto. There are no other pets in the home. The owner has been washing the pet's bedding. The dog goes to the groomer 3 times a year. The dog goes outside to potty but stays mostly on the patio. The outside yard is not fenced and there are trees and bushes on the property. No further information expected.
23-Sep-2019	UAE; 19US056666; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 12.5 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical /	13-Sep-2019	14-Sep-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, the owner reported the following event for a 12.5 pound canine (all other signalments unknown). 2006*: Started on FRONTLINE PLUS DOG 5-22 LBS (M63301AL) given topically between the shoulder blades. The owner only treated as needed. 13 Sep 2019: First dose of FRONTLINE was applied. The dog was scratching prior to the application. 14 Sep 2019: The dog was still scratching after the application. 20 Sep 2019: The owner took the dog to the veterinarian. The

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						Cutaneous **Was the product used ok?:** Yes					veterinarian said the dog had fleas and recommended giving NEXGARD (product unsubstantiated) (lot and expiration unknown). 21 Sep 2019: the dog stopped scratching. The owner is not seeing fleas in the home. The dog goes outside for potty breaks in a fenced in yard with bushes, and for walks in the neighborhood. No further medical information expected.
23-Sep-2019	UAE; 19US056681; GA; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 10.000 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	15-Aug-2019	15-Sep-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, the pet owner reported the following event for a 10 to 12 pounds *, male neutered, Shih Tzu. 15 Aug 2019: The most recent dose was applied. 15 Sep 2019: The dog was having an issue with fleas. 1 vial of FRONTLINE PLUS DOG 5-22 LBS(lot and expiration unknown, package unavailable) was applied to the dog in one area between the shoulder blades. 20 Sep 2019*: There were an unknown number of fleas on the dog. The owner bathed the dog in Dawn to kill fleas. 23 Sep 2019: There are an unknown number of fleas on the dog. The dog goes out for potty breaks in fenced in yard where the big dogs live. There are no fleas in the home. The owner has been treating monthly with FRONTLINE since Apr 2019. No further information is expected.
23-Sep-2019	UAE; 19US056706; CA; U.S.A	**Species:** Feline **Breed:** Exotic Shorthair **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 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	07-Aug-2019	09-Aug-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, a pet owner reported the following event for Nessie, a 3 year old, 10 pound, neutered male Exotic Shorthair. 7 Aug 2019: The cat received 1 application of FRONTLINE PLUS CATS (S40502AX) topically between the shoulder blades in one spot, for the first time. 9 Aug 2019*: The pet owner noticed the cat scratching and saw flea dirt on him. No fleas were noted. 7 Sep 2019: The cat received another application of FRONTLINE. 9 Sep 2019*: The cat was scratching and the owner noticed flea dirt on the cat. The cat is indoor/outdoor and the outside yard is fenced in. There are no other pets in the home. The cat receives a bath every 2 weeks. Prior to FRONTLINE the cat was receiving Revolution monthly with no issues. No further medical information expected.
23-Sep-2019	UAE; 19US056717; KY; U.S.A	**Species:** Canine **Breed:** Australian Cattle Dog **Sex:** M **Sex qualifier:** Unknown **Age:** - **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	23-Jun-2019*	24-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019 a pet owner reported the following event for Sparky, a 55 pound*, male Australian Cattle Dog cross of unknown other signalment. Jun 2019*, Jul 2019*, Aug 2019*: Owner applied FRONTLINE PLUS DOG 45-88LBS (S62111AL) to the skin between the animal's shoulder blades. Dog has continued to scratching since Jun 2019* application, but owner does not see fleas on the dog. Owner is seeing seed ticks on the dog. The dog has not been bathed. Sparky lives outside only, stays close to home, but does roam. Deer and bear are seen around the home. No fleas seen in the home. The home has not been treated, but an unknown pesticide and moth balls were placed around the perimeter of the property. Owner has applied the product on an unknown schedule for an unknown time frame to Sparky and has not had a problem with flea before. There are 2 cats in the household that live outside, are treated with Advantage II, and are also scratching. No further medical information expected.
23-Sep-2019	UAE;	**Species:** Canine	1	1	0	**Product used:**	20-Jul-2019	23-Sep-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019 the pet owner

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	19US056737; TX; U.S.A	**Breed:** Chihuahua **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 8 lbs				FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					reported the following event for an 8 pound Chihuahua mix of unknown further signalment. 20 Jul 2019: Started on FRONTLINE PLUS DOG 5-22 LBS (lot number unknown, package unavailable), 1 vial topically, in between the shoulder blades, once monthly. The pet owner was seeing an unknown number of fleas on the canine and inside the home for an unknown amount of time at the time of application. 20 Sep 2019: The most recent dose was applied. Currently the pet owner is seeing a large amount of fleas on the canine. The canine spends the majority of the time inside the home with access to a 2 ft x 6 ft flower bed. There are no other pets inside the home. No further medical information is expected.
23-Sep-2019	UAE; 19US056746; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2019*	01-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, the pet owner reported the following event for feline of unknown signalment. Sep 2019*: The pet began receiving FRONTLINE PLUS CATS (Lot unknown) (Product Unsubstantiated) on an unknown date. Owner applied 1 vial topically between the shoulder blades. Sep 2019: The owner noticed a small amount of ticks on the pet. It is unknown the status of the ticks. No further medical information expected.
23-Sep-2019	UAE; 19US056755; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** X **Sex qualifier:** Mixed **Age:** 3.00 Year(s) **Weight:** 9 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?:** Unknown to Company	14-Apr-2019*	01-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, a pet owner reported the following event in 4 cats, ranging in age from 3* to 15* years, around 9 pounds each*, one spayed female, Domestic short hair cats with further unknown signalment. 1 Apr 2019*: The owner discovered a few of the cats had fleas. 14 Apr 2019*: The owner applied FRONTLINE PLUS CATS (Lot unknown, package unavailable) in an unknown location to the cats for the first time this year. The owner uses it about once a month but not exactly every 30 days and doesn't apply it to all of the cats at the same time. The most recent application was 14 Sep 2019*. The owner has used this product seasonally between April and September* for an unknown period of years. Unknown date: The owner reports she has found several fleas on all of the cats throughout the summer on unknown dates and frequencies. She is currently seeing fleas on one cat. She brushes off several every day. The cat is asymptomatic. The other 3 cats go outdoors and mainly stay outside. There is one cat who stays indoors most of the time but also has access to the yard and porch. The owner was unable to provide further information for the case. No further medical information expected.
23-Sep-2019	UAE; 19US056758; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **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**	01-Sep-2019	02-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Sept 2019, the owner reported the following event for a, 8 pounds, male, feline (all other signalments unknown). 1 Sept 2019: The first vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) was applied between the shoulder blades, by the pet owner. It is unknown if fleas were seen at this time. 2 Sept 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 household. The cat is indoor/outdoor cat. No further medical information is expected.

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						product used ok?: Yes					
23-Sep-2019	UAE; 19US056759; MI; 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:** SC-subcutaneous **Was the product used ok?:** Unknown to Company	02-Sep-2018*	02-Sep-2018*	N/A	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, the owner reported the following event for 3 felines with unknown signalment. Sep 2018*: The owner reports that he combed off 100+ fleas on the cats. The cats were started on FRONTLINE PLUS CATS (P41204AW), topically in between the shoulder blades. 2 Sep 2018*- 23 Sep 2019*: The owner is still seeing fleas. On a daily to every other day basis, the owner is bathing and/or combing with Dawn dish soap. The cats are considered indoor cats. There were an extremely large amount of fleas seen prior to product use. The owner states that there is an active flea life cycle in the basement. There are no other pets in the home. The owner has been treating monthly with FRONTLINE since Sep 2018*. No further information at this time.
23-Sep-2019	UAE; 19US056766; FL; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 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	30-Jun-2019	01-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Sept 2019, the owner reported the following event for 2, 8 years old, 6 pounds, neutered male, feline (all other signalments unknown). Unknown date: Fleas were on cats and in the household. 30 June 2019: The cats started on FRONTLINE PLUS on a monthly basis. 31 Aug 2019: The most recent vial of FRONTLINE PLUS CATS (R40601BW) was applied between the shoulder blades, by the pet owner. 1 Sept 2019*: The cats had fleas. The cats started on another product on an unknown date and no fleas were seen anymore in the home or on the cats. It is unknown if cats are indoor only or not. No further medical information is expected.
23-Sep-2019	UAE; 19US056795; MI; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 5 - 22 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-Jun-2019*	01-Jun-2019*	22 Day(s)	D-D	Suspected Adverse Event and Lack of Efficacy Claim: On 23 Sep 2019, the pet owner reported the following event for 2 Yorkshire Terriers, 5 to 22 pounds*, all other signalments are unknown. 01 May 2019*: The owner began applying 1 vial FRONTLINE PLUS DOGS 5-22 LBS (R60308AL) to the skin between the shoulder blades monthly for the first time. 01 Jun 2019*: The owner noticed both dogs itching and dozens of live fleas. Another monthly dose was applied. The owner took both dogs to the veterinarian and was prescribed unknown allergy medication for an unknown amount of time. 01 Sep 2019*: The owner applied the most recent dose of the product. 23 Sep 2019: The owner reports seeing more fleas. These are the only 2 pets in the home. The owner bathes both dogs weekly, alternating between unknown canine flea shampoo and Dawn dish soap starting at an unknown time. The owner reports using Capstar flea/tick products after use of FRONTLINE PLUS. The house is in a suburb and owner does not rule out urban wildlife and has seen feral cats in her neighborhood. The dogs are occasionally allowed outside for brief periods. Owner has sprayed her furniture with unknown flea/tick spray. Owner reports one dog is irritated from scratching at fleas and is being treated with unknown hot spot spray. No further medical information is expected.

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23-Sep-2019	UAE; 19US056805; -; 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:** PO-Oral **Was the product used ok?:** Unknown to Company	05-Aug-2019	23-Sep-2019*	7 Week(s)	D-D	Suspected Adverse Event: On 23 Sep 2019 the pet owner reported the following event for a canine of unknown signalment. 5 Aug 2019: The owner applied FRONTLINE PLUS DOG 5-22 lbs (lot unknown). 23 Sep 2019*: The owner notices the pet was itching. It is unknown if the pet presented to the veterinarian or if treatment was given. No fleas were noticed. It is unknown if the pet received FRONTLINE PLUS before. No further information expected.
24-Sep-2019	UAE; 19US056820; 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?:** No (Treatment / vaccination program not respected)	06-Aug-2019	07-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, the owner reported the following event for 2 canines with unknown signalment. Aug 2019*: The owner noticed the pets were digging and scratching. 6 Aug 2019: The pets were started on FRONTLINE PLUS DOG 23-44 LBS (S61009AL), topically on the neck, in between the shoulder blades, and at the base of the tail. 7 Aug 2019*: The owner reported seeing a small amount of fleas on the pets. 6 Sep 2019: The most recent dose was applied. 24 Sep 2019: The owner reports that all the pets have fleas and are constantly digging and scratching. The pets are considered an indoor/outdoor as they are usually kept in a 200+ sq.ft enclosure in the backyard. There were no fleas seen prior to product use. There is 1 other dog and 2 cats in the home that are also on FRONTLINE that also have fleas (Please see cases 19US056953 & 19US056957). The owner has been treating monthly with FRONTLINE since Aug 2019. No further information at this time.
24-Sep-2019	UAE; 19US056822; GA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 17.00 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-Aug-2019	02-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sept 2019, the owner reported the following event for a 17 years old, 11 pounds, feline (all other signalments unknown). 1 Aug 2019: The cat started on FRONTLINE PLUS on a monthly basis. 1 Sept 2019: The most recent vial of FRONTLINE PLUS CATS (lot unknown, reported not queried) was applied between the shoulder blades, by the pet owner. Fleas were seen at time of application. 2 Sept 2019*: The cat had a small amount of fleas. The cat does not get bathed. The owner is not seeing any flea activity in household. The cat is indoor only but litter box is located in garage of home. It is unknown if fleas were seen before Aug application. No further medical information is expected.
24-Sep-2019	UAE; 19US056831; FL; 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 /	22-Sep-2019	23-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sept 2019, the owner reported the following event for 3 canines (all other signalments unknown). 22 Sept 2019: The first vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable) was applied between the shoulder blades, by the pet owner. No fleas were seen at time of application 23 Sept 2019*: The dogs had a small amount of fleas. The dogs do not get bathed. The owner is not seeing any flea

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						Cutaneous **Was the product used ok?:** Unknown to Company					activity in the household. The dogs have access to a hallway in an apartment complex for bathroom breaks. No further medical information is expected.
24-Sep-2019	UAE; 19US056836; KS; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.50 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	22-May-2019	23-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019 a pet owner reported the following event for Fiona, a 70 pound, 1.5 year old, spayed female, Domestic Shorthair. Apr 2019*: Owner noticed cat was scratching and had fleas after she darted out of the house and was lost in a cave. 22 May 2019: Owner started applying FRONTLINE SPRAY (P01001A) at a dose of 2 pumps per pound to Fiona. 22 Sep 2019: Owner flea combed cat and removed 35 fleas, then soaked cat with FRONTLINE SPRAY. The cat is mostly indoors, but will run out on occasion. The owner has continued to see fleas on the cat since starting the product 22 May 2019. The owner used the product one prior Apr 2018*. It is unknown if the owner has seen fleas in the home, or if the home or yard has been treated. The cat is not being bathed. There are no other animals in the home. No further medical information expected.
20-Sep-2019	UAE; 19US056838; WI; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Mixed **Age:** 3.00 Year(s) **Weight:** 10 lbs	2	2	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	06-Jul-2019	07-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim:On 20 Sept 2019, the owner reported the following event for 2, 3 years old, 10 pounds, mixed sexes, felines (all other signalments unknown). Unknown date: The owner had an infestation in the home. 6 July 2019: The cats started on FRONTLINE SPRAY on a monthly basis. 6 Sept 2019: An unknown amount of pumps of the FRONTLINE SPRAY (lot unknown, package unavailable) was sprayed all over the cats' body by the pet owner. Fleas were seen at time of application. 7 Sept 2019*: The cats had fleas. The cats do not get bathed. The owner treated the home and the yard with an unknown treatment. The cats are indoor only. There are 3 dogs in the home using FRONTLINE as well, reference case 19US056451. No further medical information is expected.
24-Sep-2019	UAE; 19US056841; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 7.5 - 11 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Aug-2018*	13-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, the owner reported the following event for two felines, 7.5 pounds and 11 pounds (all other signalments unknown). Aug 2018*: Started monthly doses of FRONTLINE PLUS CATS (S40601AX) topically between the shoulder blades, by the owner. The cats had fleas prior to the first dose. The owner continued to see fleas after the product was applied. 13 Aug 2019*: Most recent dose was applied. Unknown date: The owner switched to Advantage. The owner was still seeing a small amount of fleas on the cats. The owner was seeing fleas in the home. The cats are strictly indoor. For the last 5 months, the owner was bathing the cats with a flea shampoo and Dawn dish soap. The cats do not have any dry skin or mobility issues and there have been no visiting pets. No further medical information expected.
24-Sep-2019	UAE; 19US056855; MI; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog	1	1	0	**Product used:** FIPRONIL 10%/S	20-Jun-2019	19-Sep-2019*	29 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, a pet owner reported the following event in a 9 month old (12 Dec 2018), 90* pound, intact male, German Shepherd canine.

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		Sex: M **Sex qualifier:** - **Age:** 9.00 Month(s) **Weight:** 85 - 90 lbs				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					1 Jun 2019*: The owner discovered the dog had fleas. There are 2 cats in the house that also had fleas (see case 19US56857). 20 Jun 2019*: The owner applied FRONTLINE PLUS DOG 89-132 LBS (S62311) in between the shoulder blades to the dog for the first time this year; the owner applies it monthly around the 20th of each month. Prior to this the owner was using an off brand flea prevention on the animals. The two cats also started to receive FRONTLINE PLUS at this time. 19 Sep 2019*: The pet owner was still seeing fleas on all of the animals. Capstar was given to all of the animals. 21 Sep 2019*: The most recent application of FRONTLINE PLUS was applied to all of the animals. 22 Sep 2019*: The owner reports they continue to find more fleas on the dog every day. The dog has access to the back yard where wildlife is present; they live on 8 acres. The cats were indoor/outdoor prior to Jun 2019*. Half of the yard has been treated with an unknown pesticide. No further medical information expected.
24-Sep-2019	UAE; 19US056857; MI; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **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	20-Jun-2019*	19-Sep-2019*	29 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, a pet owner reported the following event in 2 cats with unknown signalment. 1 Jun 2019*: The owner discovered the cats had fleas. There is a dog in the house that also has fleas (see case 19US56855). 20 Jun 2019*: The owner applied FRONTLINE PLUS CATS (Lot unknown, reporter refused) in between the shoulder blades to the cats for the first time this year; the owner applies it monthly around the 20th of each month. Prior to this the owner was using an off brand flea prevention on the animals. The dog also started to receive FRONTLINE PLUS at this time. 19 Sep 2019*: The pet owner was still seeing fleas on all of the animals. Capstar was given to all of the animals. 21 Sep 2019*: The most recent application of FRONTLINE PLUS was applied to all of the animals. 22 Sep 2019*: The owner reports they continue to find more fleas on all of the animals every day. The dog has access to the back yard where wildlife is present; they live on 8 acres. The cats were indoor/outdoor prior to Jun 2019*. Half of the yard has been treated with an unknown pesticide. No further medical information expected.
24-Sep-2019	UAE; 19US056859; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 20 - 80 lbs	3	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Pet Armor; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Sep-2019	08-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, the pet owner reported the following event for a 14 year old*, 20 pound*, West Highland Terrier of further unknown signalment, a 14 year old, 20 pound*, Shih Tzu of further unknown signalment, a 13 year old, 20 pound*, Pug of further unknown signalment, and a 9 year old*, 80 pound*, canine of further unknown signalment. Unknown dates: All four dogs were receiving unknown Pet Armor (flea control product) applied monthly on unknown dates, year round; however, the last date the product was respectively applied on all four dogs was on an unknown date likely between 1 Aug 2019* and 7 Aug 2019*. It's also possible that the Aug 2019 application was applied up to one week late, but the reporter cannot be certain. Despite monthly Pet Armor use, on unknown dates, the canines were experiencing break-through itching; it's unknown if fleas were seen on any of the dogs at the time of or after Pet Armor use. 7 Sep 2019: The three dogs weighing around 20 pounds each received one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown; package unavailable) applied topically between the

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											shoulder blades for the first time. The 80 pound* canine also received one vial of FRONTLINE PLUS 45-88 LBS (lot unknown; package unavailable) applied topically between the shoulder blades for the first time. At the time of FRONTLINE PLUS, all four dogs were pruritic and at least one of the dogs had a few fleas present. It cannot be confirmed if any of the other three dogs had fleas present. Unknown dates: An unknown duration following multiple FRONTLINE PLUS product use, the pet owner has observed an increased volume of fleas on at least one of the dogs. It's unknown the dogs' pruritus has changed since product application. About three weeks after FRONTLINE PLUS was applied to all four canines, a dog named Jackson was bathed with an unknown dog shampoo because a medium volume of fleas were present on its body. It cannot be confirmed which of the four
24-Sep-2019	UAE; 19US056874; AZ; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 80 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown brand of shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Sep-2019	15-Sep-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019 the pet owner reported the following event via mail for an 80 pound male canine of unknown further signalment. 12 Sep 2019*: The pet owner discovered an unknown number of tick on the canine and bathed him with an unknown brand of shampoo. A pest control service treated the inside of the home and yard. 13 Sep 2019*: The pet owner applied FRONTLINE PLUS DOG 45-88 LBS (S61810RX) (invalid lot number), 1 dose, topically, in between the shoulder blades. A pest control service treated the inside of the home and yard. 15 Sep 2019: The pet owner is still seeing an unknown number of ticks on the canine. Currently, it is unknown if the pet owner is still seeing ticks. It is also unknown where the canine spends the majority of the time or what outside areas he might have access to. No further medical information is expected.
24-Sep-2019	UAE; 19US056887; IL; U.S.A	**Species:** Canine **Breed:** Dachshund **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 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?:** Yes	19-Sep-2019	20-Sep-2019	1 Day(s)	D-D	Suspected Adverse Event: On 24 Sep 2019 a pet owner reported the following event for Buddy, a 23 pound, 10 year old, neutered male Dachshund cross. 19 Sep 2019: Owner applied FRONTLINE PLUS DOG 23-44 LBS (S61727AL) to the skin between the animal's shoulder blades for the first time. 20 Sep 2019: Dog started scratching excessively, to the point of creating scabs on himself. Owner has not seen any fleas on the dog. Owner is treated at home with diphenhydramine and Neosporin to the scabs, but the symptoms persist. No further medical information expected.
24-Sep-2019	UAE; 19US056919; PA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** X **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 11 - 15 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	25-Aug-2019	13-Sep-2019	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, a pet owner reported the following event in 2 cats, one 6 year old*, 15 pound*, neutered male, Domestic Shorthair feline and one 9 year old*, 11 pound*, spayed female Domestic Shorthair feline. 25 Apr 2019*: The owner started to apply an unknown flea prevention to the cats monthly. The owner uses flea prevention seasonally from April to November every year.There are 3 dogs in the home that are also on flea prevention. One dog is on an unknown oral monthly prevention and the other dogs wear Seresto collars. 25 Aug 2019: The owner applied FRONTLINE PLUS CATS

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						product used ok?: No (Treatment / vaccination program not respected)					(S41404AW) in between the shoulder blades to the cats for the first time this year. 13 Sep 2019: The owner noticed there were fleas on both of the cats. 14 Sep 2019: The owner applied FRONTLINE PLUS CATS (S41404AW) in between the shoulder blades to the cats. 23 Sep 2019: The owner reports they found fleas on both of the cats. They are also seeing flea dirt. The cats do get out on occasion. The dogs have access to the back yard regularly. There is vegetation and grass. The owner has not seen fleas on the dogs but she suspects they have fleas. They are in a wooded area where a lot of wildlife is present. No further medical information expected.
24-Sep-2019	UAE; 19US056928; -; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 17.00 Year(s) **Weight:** 11 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** AFOXOLANER 11.3 MG CHEWABLE TABLETS; **Route:** unknown **Was the product used ok?:** Unknown to Company	20-Aug-2019*	20-Sep-2019*	31 Day(s)	D-C	Suspected Adverse Event: On 24 Sep 2019, the pet owner reported the following event for a 17 year old, 11 pound, female, Yorkshire Terrier of further unknown signalment. Unknown dates: The patient received unknown FRONTLINE PLUS (lot unknown; reporter refused) (product unsubstantiated). The volume, route, location, and frequency of product administration could not be obtained because the reporter refused; however, an efficacy concern involving the product was reported. Please see case 19US057053 for details. 20 Sep 2019: The canine received one chew of unknown NEXGARD (lot and expiration unknown; reporter refused) (product unsubstantiated), PO with food for the first time. An unknown duration following NEXGARD ingestion when the reporter came back home, the canine had become nervous and was shaking and an unknown duration thereafter, vomited up the NEXGARD chew as well as her food. Presently, the canine's status is unknown. The reporter does not suspect NEXGARD to be the cause of the dog's symptoms, citing that the canine prefers to be around at least one of the pet owners at all times and has a history of acting nervous and shaking any time she's not with one of said pet owners. No further medical information expected.
24-Sep-2019	UAE; 19US056940; -; 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:** unknown **Was the product used ok?:** Unknown to Company	16-Sep-2019*	23-Sep-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, the pet owner reported the following event for 1 female cat, all other signalments are unknown. 01 Jul 2019*: The owner applied contents of 1 vial FRONTLINE PLUS CATS (unsubstantiated) between the shoulder blades for the first time monthy. 16 Sep 2019*: The owner applied the most recent dose of the product. 23 Sep 2019: The owner reports still seeing fleas on the cat and combing them off. It is unknown if there are any other pets in the household. The environment is unknown. It is also unknown if the cat is being bathed. No further information at this time.
24-Sep-2019	UAE; 19US056948; PA; 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	18-Sep-2019	24-Sep-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019 the pet owner reported the following event for a feline of unknown signalment. 18 Sep 2019: The pet owner applied FRONTLINE PLUS CATS (lot number unknown, package unavailable), 1 vial topically, in between the shoulder blades for the first time. No fleas were seen at the time of application. 24 Sep 2019: The pet owner began seeing a small amount of fleas on the feline.

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						Route: Topical / Cutaneous **Was the product used ok?:** Yes					The feline spends the entirety of its time inside the home. There are no other pets inside the home. No further medical information is expected.
24-Sep-2019	UAE; 19US056950; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 14 - 15 lbs	4	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	20-Sep-2019	24-Sep-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sept 2019, the pet owner reported the following event for a 14 pound and 15 pound feline of further unknown signalment. 20 Sept 2019: The pet owner applied a dose of FRONTLINE PLUS CATS (lot unknown, not queried). It is unknown if the cats had fleas at this time. 24 Sept 2019: The cats had a large number of fleas. There are 2 other smaller cats in the home who are also treated and do not have fleas. It is unknown if the cats have received FRONTLINE prior. No further medical information expected.
24-Sep-2019	UAE; 19US056957; MI; U.S.A	**Species:** Feline **Breed:** - **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 (Treatment / vaccination program not respected)	06-Aug-2019	24-Sep-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, the owner reported the following event for 2 felines with unknown signalment. Aug 2019*: The owner noticed the pets were digging and scratching. 6 Aug 2019: The pets were started on FRONTLINE PLUS CATS (S40606AW), topically on the neck, in between the shoulder blades, and at the base of the tail. 7 Aug 2019*: The owner reported seeing a small amount of fleas on the pets. 6 Sep 2019: The most recent dose was applied. 24 Sep 2019: The owner reports that all the pets have fleas and are constantly digging and scratching. The pets are considered an indoor/outdoor as they are usually kept in a 200+ sq.ft enclosure in the backyard. There were no fleas seen prior to product use. There are 3 other dogs in the home that are also on FRONTLINE that also have fleas (Please see cases 19US056820 & 19US056953). The owner has been treating monthly with FRONTLINE since Aug 2019. No further information at this time.
24-Sep-2019	UAE; 19US056985; MN; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 10 - 15 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2018	31-Jul-2019*	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, the owner reported the following event for two felines, approx. 10 and 15 pounds (all other signalments unknown). Sep 2018*: Started on monthly doses of FRONTLINE PLUS CATS (S40815BW) topically between the shoulder blades, by the owner. 1 Jul 2019: Another dose of FRONTLINE was applied. 31 Jul 2019*: The owner started seeing fleas on the cats. 1 Sep 2019: Most recent dose of FRONTLINE was applied. The owner is still seeing fleas on the cats. The owner is seeing fleas in the home. The owner has treated the home with Knockout Spray. The cats are strictly indoor. The owner bathes the cats once a month with a flea and tick shampoo. 1 of the cats has some dry skin issues. No further medical information expected.
24-Sep-2019	UAE; 19US056990; IL; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	01-Sep-2019	07-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, the pet owner reported the following event for Daisy, a 2.5 years old, 36 pound female (reproduction status unknown) canine. 1 July 2018*: The pet began receiving FRONTLINE PLUS DOG 23-44 LBS (lot unknown) (package unavailable) applied 1 vial

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		Unknown **Age:** 2.50 Year(s) **Weight:** 36 lbs				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					topically between the shoulder blades. 1 Sep 2019: The pet received a monthly dose FRONTLINE PLUS DOG 23-44 LBS (S62704AW) 1 vial topically between the shoulder blades. 7 Sep 2019*: The owner took the pet for a walk on a wooded trail. The owner noticed a small amount of fleas on the pet. 13 Sep 2019: The pet received a flea bath with a dog flea shampoo and another dose of FRONTLINE PLUS DOG 23-44 LBS was applied. The owner has been noticing a small amount fleas off of the pet inside the home. The yard is fenced and treated with pesticides every 3 months. The pet is treated monthly, year-round. No further medical information expected.
24-Sep-2019	UAE; 19US056995; CA; U.S.A	**Species:** Canine **Breed:** Pomeranian **Sex:** M **Sex qualifier:** Neutered **Age:** 16.00 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	08-Aug-2019	09-Aug-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, the pet owner reported the following event for Shiro, a 16 year old (neutered male), 14 pound, Pomeranian. Unknown date: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (S61902AL) monthly. It is unknown if the product is applied year round. 8 Aug 2019: Another dose of FRONTLINE was applied directly on the skin between the shoulder blades. Fleas were seen prior to product application. 9 Aug 2019*: The pet owner is continuing to see fleas. 11 Sep 2019: The most recent date of FRONTLINE application. The owner is still noticing a moderate amount of fleas on the dog, but is not seeing any fleas in the home. The dog has access to a fenced in yard, with hedges in the yard. The dog does not go on walks or to the dog park. The pet owner did bathe the dog with a flea shampoo. No further medical information expected.
24-Sep-2019	UAE; 19US057009; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **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	19-Jan-2019*	24-Aug-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, the pet owner reported the following event for Pip, 8 pound canine of unknown signalment. Jan 2019*: The pet began receiving monthly FRONTLINE PLUS 5-22 LBS (Lot unknown) (package unavailable). Owner applied 1 vial topically between the shoulder blades. 20 Aug 2019*: Another vial was applied. 24 Aug 2019*: The owner noticed moderate amount of fleas on the pet. The pet was very itchy. 20 Sep 2019*: The most recent dose was applied FRONTLINE PLUS 5-22 LBS (S61203AX). The owner has been noticing fleas off of the pet inside the home . Family members are being bitten. The pet has access to a fenced yard. The pet has presented to the veterinarian for the scratching. The pet received baths every 3 months. There a total of 2 canines and 1 feline in the household. See cases 19US057054 and 19US057056. No further medical information expected.
24-Sep-2019	UAE; 19US057011; -; 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 /	01-Aug-2019*	24-Sep-2019	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sept 2019, the pet owner reported the following event for a female feline of further unknown signalment. 1 Aug 2019*: First dose of FRONTLINE PLUS CATS (lot unknown, not queried) was applied. It is unknown if there were fleas on the cat at that time. 24 Sept 2019: The cat had fleas. It is unknown how many other cats are in the home. Those cats are on Advantage 2 and do not have fleas. It is unknown if the cats go outside

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						Cutaneous **Was the product used ok?:** Unknown to Company					No further medical information expected.
24-Sep-2019	UAE; 19US057018; CA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 13 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Human shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Sep-2019	17-Sep-2019	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019 a pet owner reported the following event for Winston, a 13 pound, male canine of unknown other signalment. 5 Sep 2019: Owner applied FRONTLINE PLUS DOG 5-22 LBS (S61902AL) to the skin between the animal's shoulder blades. 17 Sep 2019: Owner saw approximately 20 live fleas on the dog, bathed in human shampoo, and applied FRONTLINE again. 23 Sep 2019: Dog was chewing from fleas and owner saw 5 fleas on the dog. The owner has been using the product monthly since Apr 2019*. There are no other animals in the home, but owner lives in a building where there are other dogs who share common areas inside the building. The dog goes outside on a leash to go potty in a grassy area. The owner does not know if there is wildlife on the grounds. No fleas seen in the home and the home has not been treated. No further medical information expected.
24-Sep-2019	UAE; 19US057030; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** puppy shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2019	01-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 September 2019, the owner reported the following event for a 10 year old male dog (signalment unknown). 1 Sept 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S61203AX) was applied to the skin between the shoulder blades. *Unknown date: The dog picked up 10 fleas. The dog is exposed to a grass yard daily and there aren't any fleas in the home. The dog is bathed once a month in puppy shampoo. No further information available.
24-Sep-2019	UAE; 19US057041; TX; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 2 - 4 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Dawn; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	02-Sep-2019	17-Sep-2019*	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 September 2019, the owner reported the following event for 2 cats weighing 2 and 4 pounds(signalment unknown). 2 September 2019: One vial of FRONTLINE PLUS CATS (S41003AW) was applied to the skin between the shoulder blades. *17 September 2019: The cats started to pick up a few fleas. The cats are indoor and outdoor and have access to a grass yard and side walks. The cats are treated monthly year round and are bathed once a month in Dawn. There are no fleas in the home or any other cats or dogs. No further information available.
24-Sep-2019	UAE; 19US057049; OH; U.S.A	**Species:** Canine **Breed:** Norfolk Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	22-Sep-2019	23-Sep-2019	1 Day(s)	D-C	Suspect Adverse Event: On 24 Sep 2019, the owner reported the following event for Winston, a 4 year old*, 40 pound, neutered male, Norfolk Terrier. 2017*: The dog was given a half of a vial of FRONTLINE PLUS FOR DOGS 23-44 LBS (lot unknown, package unavailable). The dog vomited. The dog recovered. 22 Sep 2019: One half of a vial of FRONTLINE PLUS FOR DOGS

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		Weight: 40 lbs				products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected)					23-44 LBS (R60516) was applied between the shoulder blades at 6:00PM CST. Between 1:30AM-1:45AM CST the dog vomited. 10 minutes lated the dog became stiff, would not move, and was unresponsive. Owner was able to get dog to respond. Dog had diarrhea and began to pant heavily. The dog presented to the emergency veterinarian. The dog was tender in the the abdomen when palpated and was treated with Cerenia. 24 Sep 2019: The dog recovered. No further medical information expected. UPDATE 25 Sep 2019: Per veterinarian the dog has received the product since 2017 with no issue. No further medical information expected.
24-Sep-2019	UAE; 19US057053; -; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 17.00 Year(s) **Weight:** 11 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	20-Aug-2019*	21-Aug-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, the pet owner reported the following event for a 17 year old, 11 pound, female, Yorkshire Terrier of further unknown signalment. Unknown dates: The patient received unknown FRONTLINE PLUS (lot unknown; reporter refused) (product unsubstantiated). The volume, route, location, and frequency of product administration could not be obtained because the reporter refused; however, the canine has previously received the product. It cannot be confirmed if fleas were present at the time of any of the FRONTLINE PLUS applications. An unknown duration following the most recent unknown date of product application, the reporter's wife found a single flea on the canine. She subsequently bathed the patient with an unknown shampoo and an unknown duration thereafter, the canine was switched and treated with unknown NEXGARD (lot and expiration unknown; reporter refused) (product unsubstantiated), PO. Presently, it's unknown if the canine continues to pick up fleas. An adverse event following unknown NEXGARD administration was also reported. Please see case 19US056928 for details. It's unknown if there are any other animals in the home. The canine is often outside laying in the yard and in the ivy. She also travels often via airplane to unknown destinations with the reporter. No additional details regarding the dog's external, resident internal, and variable internal environments could be obtained. Likewise, this is the extent of the information available because the reporter refused to provide anything additional. No further medical information expected.
24-Sep-2019	UAE; 19US057054; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 78 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Aug-2019*	24-Aug-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, the pet owner reported the following event for Charlie, 78 pound canine of unknown signalment. Jan 2019*: The pet began receiving monthly FRONTLINE PLUS 45-88 LBS (Lot unknown) (package unavailable). Owner applied 1 vial topically between the shoulder blades. 20 Aug 2019*: Another vial was applied. 24 Aug 2019*: The owner noticed moderate amount of fleas on the pet. 20 Sep 2019*: The most recent dose was applied FRONTLINE PLUS 45-88 LBS (S61203AX). The owner has been noticing fleas off of the pet inside the home . Family members are being bitten. The yard is fenced. The pet received baths every 3 months. There a total of 2 canines and 1 feline in the household. See cases 19US057009 and 19US057056. No further medical information expected.

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24-Sep-2019	UAE; 19US057056; -; U.S.A	**Species:** Feline **Breed:** - **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 3 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	19-Aug-2019*	24-Aug-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, the pet owner reported the following event for Angel, 3 pound feline of unknown signalment. Jan 2019*: The pet began receiving monthly FRONTLINE PLUS CAT (Lot unknown) (package unavailable). Owner applied 1 vial topically between the shoulder blades. 20 Aug 2019*: Another vial was applied. 24 Aug 2019*: The owner noticed moderate amount of fleas on the pet. 20 Sep 2019*: The most recent dose was applied FRONTLINE PLUS CAT (S40601AX). The owner has been noticing fleas off of the pet inside the home . Family members are being bitten. The cat in indoor/outdoor. The yard is fenced. There a total of 2 canines and 1 feline in the household. See cases 19US057054 and 19US057009. No further medical information expected.
24-Sep-2019	UAE; 19US057065; TX; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 5 - 22 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Oatmeal Medicated Moisturizing Shampoo for dogs; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Contraindication per label)	23-Mar-2016*	24-Mar-2016*	N/A	D-C	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 24 Sep 2019 a pet owner reported the following event for Pete, a 5 to 22 pound, 12 year old*, male Chihuahua cross of unknown other signalment. 2009*: Dog started receiving FRONTLINE PLUS DOG 5-22 LBS (S60401) monthly. 2016*: Dog started experiencing seizures that the owner describes as always occurring when Pete is sleeping. He wakes up and notifies owner by putting his paw on her. Then, he falls over on the bed and is stiff. The episode lasts for approximately two minutes, which includes the postictal phase. Unknown Date: Pete presented to a clinic for the seizures, blood work was performed which was WNL, and the owner was told to just keep an eye on the seizures for increase in frequency. 23 Mar 2019: Owner applied FRONTLINE PLUS DOG 5-22 LBS, half the vial to the skin between the animal's shoulder blades and half to the skin between the hips. Mar 2019*: Owner started noticing 5 fleas on the dog when she flea comes him once a week. The owner is continuing to see fleas. She has been using the product monthly for 10 years and this is the first time the dog has had fleas. Owner has been treating the yard and home with pesticide for 2 months. The owner has not seen fleas in the home other than seeing flea dirt on the dog's bedding. The dog lives inside with access to a dog door to go outside in the fenced in yard with grass and trees. The dog also go for walks in the neighborhood. The owner sees deer in the yard. The owner bathes the dog in Oatmeal Medicated Moisturizing Shampoo for dogs once a month or less, always 2 weeks after FRONTLINE application. There are two other dogs in the home who have their own case: 19US057052. Pete continued to have seizures every 6 to 7 months. No further medical information expected. UPDATE 7 OCT 2019: Corrected case to serious.
24-Sep-2019	UAE; 19US057068; CA; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	01-Sep-2019*	24-Sep-2019	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, the pet owner reported the following event for a 12 year old male Maltese/ Toy Poodle mix with otherwise unknown signalment. Unknown date: The dog began receiving FRONTLINE PLUS DOG (unsubstantiated) (lot unknown, package unavailable) monthly with unknown purchase history. Product application details are unknown. It is unknown if fleas were seen prior to product application.

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						products **Route:** unknown **Was the product used ok?:** Unknown to Company					It is unknown which flea prevention product the dog has received most recently, nor the application date. 24 Sep 2019: The owner is still noticing severe fleas. The dog's excursion details are unknown. It is unknown if the dog has presented to the veterinary clinic. It is unknown if treatments have been provided at home. It is unknown how many animals are in the household. The pet owner admits that the dog routinely receives different flea prevention products, since she will purchase whatever is most convenient. She did not provide the name for other products used. It is unknown when FRONTLINE PLUS was last applied, but her dog has continued to have a flea infestation. No further medical information expected.
24-Sep-2019	UAE; 19US057069; PA; U.S.A	**Species:** Canine **Breed:** Beagle **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 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	17-May-2019	17-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 24 Sep 2019, a pet owner reported the following event for Tommmy, a 35 pound, 10 year old, neutered male, Beagle. 17 May 2019: The pet owner started seeing a large amount of fleas in her home and on the dog. The dog is indoor/outdoor. He has access to a fenced in backyard with grass. The dog spends the majority of his time indoors. The owner purchased and applied for the first time FRONTLINE PLUS DOG 23-44 LBS (unknown lot number, package unavailable) with 1 dose applied topically between the shoulder blades. 17 Jun 2019: The owner applied 1 dose of FRONTLINE to the dog she was still seeing the same amount of fleas on her dog and inside of her home. 17 Jul 2019: The owner applied 1 dose of FRONTLINE to the dog she was still seeing the same amount of fleas on her dog and inside of her home. 17 Aug 2019: The owner applied the most recent dose of FRONTLINE to the dog she was still seeing the same amount of fleas on her dog and inside of her home. The pet owner treated her home with an unknown pesticide. The pet owner stopped the use of the product and switched her dog to FRONTLINE GOLD DOG 23-44 LBS on the 17 Sep 2019. The owner is still seeing a large life cycle on the dog and inside of her home see case 19US057063. No further medical information expected.
24-Sep-2019	UAE; 19US057070; PA; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 Month(s) **Weight:** 19 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unspecified oatmeal based flea shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Sep-2019	23-Sep-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019 an animal owner reported the following event in Chewy, a 19 pound, 14 month old, male neutered, Pomeranian mix. 16 Sep 2019: The animal owner saw fleas on canine. The canine was bathed with an unspecified flea shampoo. 18 Sep 2019: The canine was administered FRONTLINE PLUS DOGS 5-22 LBS (S63009BL) between the shoulder blades. There were fleas on canine at time of administration. 23 Sep 2019: The animal owner saw fleas on canine. The canine was bathed with an unspecified flea shampoo. The canine has been receiving monthly doses of FRONTLINE PLUS DOGS since a puppy without issue. There are no other pets in the household. The canine has access to outdoors. No further information provided nor expected.
24-Sep-2019	UAE; 19US057073;	**Species:** Canine **Breed:** Setter	2	1	0	**Product used:** FIPRONIL	21-Sep-2019	24-Sep-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, a pet owner reported the following event for Kate, a 2.5 year old, 70 pound,

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	PA; U.S.A	(Irish) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.50 Year(s) **Weight:** 70 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					spayed female Irish Setter. 2017*: The dog began receiving monthly year round applications of FRONTLINE PLUS DOG 45-88 LBS (S60502AX) topically between the shoulder blades in one spot. 21 Sep 2019: The owner noticed 4 live fleas on the dog and applied a dose of FRONTLINE. 24 Sep 2019: The owner saw 2 small live fleas on the dog. There is 1 other dog in the home that receives FRONTLINE but the owner is not seeing fleas on that dog. The outside yard is fenced in and there are no decks or crawl spaces on the property. There is no flea activity inside the home. The dog goes to the groomer 3 times a year. The dog's most recent grooming visit was the beginning of August. No further information expected.
25-Sep-2019	UAE; 19US057101; NC; U.S.A	**Species:** Canine **Breed:** Schnauzer (Miniature) **Sex:** U **Sex qualifier:** Unknown **Age:** 14.00 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	16-Sep-2019	24-Sep-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sept 2019, the owner reported the following event for a 14 years old, 15 pounds, Schnauzer/ Poodle Crossbreed (all other signalments unknown). Unknown date: The dog was itching but no fleas were seen. 16 Sept 2019: The first vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable) was applied between the shoulder blades, by the pet owner. No fleas were seen at time of application. 24 Sept 2019: The dog had one flea. The owner removed that flea and place it in water and it was still alive the following morning. The dog does not get bathed. The owner is not seeing any flea activity in the household.It is unknown where the dog has access to for bathroom breaks. No further medical information is expected.
24-Sep-2019	UAE; 19US057112; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2019*	02-Jan-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, the pet owner called and reported the following for 2 dogs of unknown signalment. Unknown date: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (unsubstantiated) (lot unknown, reporter refused). An unknown volume per animal via an unknown route at an unknown location. On an unknown date, the pet owner started to see fleas on both canines. It is unknown if they presented to a veterinary clinic or received any treatment. Their current condition is unknown. This is the extent of information known as caller refused to report. Pet owner reported other cases - 19US057061, 19US057127, 19US057130. No further medical information expected.
25-Sep-2019	UAE; 19US057119; PA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	8	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	12-Sep-2019	25-Sep-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, the pet owner reported the following event for a domestic shorthair feline. All other signalments unknown. 12 Sep 2019: It is unknown if the cats were having an issue with fleas prior to FRONTLINE PLUS CATS(lot and expiration unknown, reporter not queried). 25 Sep 2019: The one saw 1 flea on a cat an flea dirt. There are 8 other cats in the home,. It is unknown how long the cats have been treated with FRONTLINE, the pet owner declined to complete the report. No further information.

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25-Sep-2019	UAE; 19US057123; NY; U.S.A	**Species:** Canine **Breed:** Shepherd Dog (Others) **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 67 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Sep-2019*	19-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, the pet owner reported the following event for Maggie, a 12 year old, Spayed Female, 67 pound, Belgian Shepherd. 18 Sep 2019*: The dog began receiving FRONTLINE PLUS DOG 45-88 LBS (T60408AX) monthly for this season. The product was applied directly on the skin between the shoulder blades. 19 Sep 2019*: The owner is noticing fleas. The dog has access to a large fenced in yard, no trees or brush on the property, raccoons and opossums do come in the yard. The dog does go for walks in the neighborhood. The dog's current condition is ongoing. There are no other pets in the household. The client is concerned the product is expired. The dog has a pertinent medical history of dry skin. The dog has no history of drug or vaccine reactions. No further medical information expected.
24-Sep-2019	UAE; 19US057127; -; U.S.A	**Species:** Canine **Breed:** Doberman **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2019*	01-Jan-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Sep 2019, the pet owner called and reported the following for 2 dogs of unknown signalment. Unknown date: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (unsubstantiated) (lot unknown, reporter refused). An unknown volume per animal via an unknown route at an unknown location. On an unknown date, the pet owner started to see fleas on both canines. It is unknown if they presented to a veterinary clinic or received any treatment. Their current condition is unknown. This is the extent of information known as caller refused to report. Pet owner reported other cases - 19US057112, 19US057061, 19US057130. No further medical information expected.
25-Sep-2019	UAE; 19US057128; OH; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **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	06-Sep-2019	07-Sep-2019	1 Day(s)	D-D	Suspected Adverse Event:On 25 Sept 2019, the owner reported the following event for a canine (all other signalments unknown). 6 Sept 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, reporter not queried) was applied between the shoulder blades, by the pet owner. 7 Sept 2019: The dog started to itch. The owner is not seeing any fleas on the pet but the coat of the dog is every thick. No further medical information is expected. UPDATE 10 Oct 2019: Per information received from the pet owner, 6 Sep 2019: Contrary to what was originally reported, the pet owner applied FRONTLINE PLUS DOG 89-132 LBS (lot number unknown, package unavailable), 1 dose topically, in between the shoulder blades for the first time to the 90 pound canine. Also contrary to what was originally reported, at the time of application a large amount of fleas were seen on the canine and none inside the home. 6 Oct 2019: The second dose was applied. 10 Oct 2019: Currently, the pet owner is still seeing a large number of fleas on the pet and a small number inside the home. The canine spends the majority of the time inside the home with access to an outside lawn. There are no other pets in the household. No further information is expected.
25-Sep-2019	UAE; 19US057136; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products**	05-Sep-2019*	25-Sep-2019*	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, the pet owner reported the following event for Chessie, a 13 years old*, 10 pound*, female feline of unknown breed. 1 Jun 2019*: The pet began receiving monthly FRONTLINE PLUS CAT (S41307AW). Owner applied 1 vial topically between the shoulder blades, for the first time. Fleas were not seen prior to

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		Age: 13.00 Year(s) **Weight:** 10 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					application. 5 Sep 2019*: The most recent dose was applied. 25 Sep 2019*: The owner noticed a small amount of fleas on the pet. The pet status is ongoing. The pet lives in the garage year-round. The pet is experiencing dermatitis, developed red bumps from being bitten. The pet has not presented to the veterinarian. No further medical information expected.
25-Sep-2019	UAE; 19US057145; -; 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:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	11-Sep-2019*	25-Sep-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, a pet owner reported the following event for an 18 pound canine, further signalment unknown. 11 Sep 2019*: The dog received 1 application of FRONTLINE PLUS DOG 5-22 LBS (Unsubstantiated) (Lot Unknown, Package Unavailable) topically between the shoulder blades in one spot. It is unknown if this was the first application of the year or if the dog has received FRONTLINE in the past. It is unknown if fleas were noticed on the dog prior to application. 25 Sep 2019*: The pet owner is noticing an unknown amount of live fleas on the dog. The dog is chewing at his hind end and scratching. It is unknown if there are any other pets in the house. It is unknown what the outside environment is like. It is unknown how much exposure the dog has outside. It is unknown if there is any flea activity inside the home. It is unknown if the dog receives baths. No further information expected.
25-Sep-2019	UAE; 19US057149; MA; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jul-2019*	25-Jul-2019*	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, the pet owner reported the following event for a male neutered, domestic medium hair. 1 Jul 2019*: 1 vial of FRONTLINE PLUS CATS (lot and expiration unknown, package unavailable) was applied to the cat in one area between the shoulder blades. 25 Jul 2019*: The cat was taken to the vet where fleas and flea dirt were noted on the cat. The cat was switched to a different product. The owner has been treating with FRONTLINE for an unknown number of year and has never seen fleas on the cat. The cat is primarily outdoors, it is unknown what area's he frequents .There are no fleas dint he home. No further information is expected.
25-Sep-2019	UAE; 19US057193; LA; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 22.000 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn baths; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	23-Aug-2019	01-Sep-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, the pet owner reported the following event for Romeo, a 14 years old, 22 pound*, male canine of unknown signalment. 23 Jul 2019*: The pet began receiving monthly FRONTLINE PLUS DOG 5-22 LBS (S63009BL) with a 6 pack purchased from an unknown source. Owner applied 1 vial topically between the shoulder blades. 23 Aug 2019: The monthy dose was applied. Sep 2019*: Owner was noticing fleas on the pet. Owner gave bathes with Dawn dish soap every other day. 23 Sep 2019: The most recent dose was applied. 25 Sep 2019*: The owner noticed moderate (10-20) amount of fleas on the pet. There a total of 3 canines. Two other canine live outdoors and are not treated. The yard is about 5 acres. The owner has been treating the pet monthly for an unknown duration of time without seeing fleas. No further medical information expected.

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25-Sep-2019	UAE; 19US057225; PA; U.S.A	**Species:** Canine **Breed:** Spaniel (Cocker) **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 23 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown Flea Shampooo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2019	22-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019 a pet owner reported the following event for a 23 pound, 8 month old, male Cocker Spaniel of unknown other signalment. 1 Sep 2019*: Owner applied FRONTLINE PLUS DOG 23-44 LBS (lot unknown, Package unavailable) to the skin between the animal's shoulder blades. 22 Sep 2019: Owner noticed fleas on the dog, gave the dog a flea bath with unknown flea shampoo, and applied FRONTLINE PLUS DOG 23-44 LBS (lot unknown, Package unavailable) to the skin between the animal's shoulder blades which was 3 weeks after last application. 24 Sep 2019: Owner bathed the dog with unknown flea shampoo. Owner saw 5-10 fleas in the water, but unknown if live or dead, and when blow drying dog afterwards saw 25 dead fleas. 25 Sep 2019: Dog is still scratching and has fleas. Owner is seeing 3-4 fleas at a time on his belly. Owner is seeing fleas in the home and they are biting the owner. The dog lives inside, going outside into a fenced in yard with grass and bushes with mulch around them. Owner sees rabbits, squirrels, and has seen a raccoon in the yard. There are no other animals in the home. The owner has not treated the home or the yard. The owner has been using the product monthly since Jan 2019*. No further medical information expected.
25-Sep-2019	UAE; 19US057239; TX; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 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	01-Sep-2019	25-Sep-2019	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, the owner reported the following event for Squiggles, a female neutered, 8 pound, 8 year old, Shih Tzu. 1 Sep 2019: One vial of the FRONTLINE PLUS DOG 5-22 LBS (36902AL) was applied topically in between the shoulder blades by the owner. 25 Sep 2019: The owner noticed a large amount of fleas were seen on the dog. Owner purchased 6 pack on the 1st of September. The dog is indoor mostly and is walked on a leash for potty breaks and recreation. Fleas are not seen within the home and wildlife is not seen within the area. The owner uses the product when she feels it is needed. The owner used the product once before at an unknown date 6 months prior.No further medical information is expected.
25-Sep-2019	UAE; 19US057240; CA; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** F **Sex qualifier:** Neutered **Age:** - **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2019*	25-Sep-2019*	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, the pet owner reported the for a 10 pound, female spayed, domestic medium hair. 1 Jul 2019*: The cat was having an issue with fleas. The owner applied 1 vial of FRONTLINE PLUS CAT (S40503AX) to the cat in one area between the shoulder blades for the very first time. Aug 2019: There were fleas on the cat. 1 vial was applied. 1 Sep 2019*:There were fleas on the cat. The most recent vial was applied. 25 Sep 219: The pet owner reports she has been seeing fleas on the cat daily since the applications. The cat is indoor only. There are fleas in the home biting the humans. No further information is expected.
25-Sep-2019	UAE; 19US057250; IA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON	05-Sep-2019	06-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sept 2019, the owner reported the following event for a feline (all other signalments unknown). Unknown date: The cat was scratching. 5 Sept 2019: The first vial of FRONTLINE PLUS CATS (lot

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		Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					unknown, reported not queried) was applied between the shoulder blades, by the pet owner. 6 Sept 2019*: The cat had fleas. The cat does not get bathed. The owner is noticing flea activity in the home. It is unknown if the cat goes outdoor. No further medical information is expected.
25-Sep-2019	UAE; 19US057253; VA; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 10.8 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** AFOXOLANER 28.3 MG CHEWABLE TABLETS; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	25-May-2019*	09-Sep-2019*	15 Day(s)	D-D	Suspected Lack of Efficacy Claim and adverse event: On 25 Sep 2019 a pet owner reported the following event for Baxter, a 10.8 pound, 10 year old, neutered male Yorkshire Terrier. May 2019* to Aug 2019*: Owner applied FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable) topically in an unknown location. 9 Sep 2019*: Dog returned home from boarding and grooming and owner started noting fleas on the dog. 23 Sep 2019: Dog received 1 chew NEXGARD (28.3 mg) (lot and expiration unknown, package unavailable) PO for the first time. 24 Sep 2019: Dog began scratching intensely to the point of making his skin red. 25 Sep 2019: In the morning the owner saw 3 live fleas on the dog. The owner has treated the home and yard. There is an indoor only cat in the home who does not have fleas and received Revolution. No further medical information expected.
25-Sep-2019	UAE; 19US057267; PA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	11-Sep-2019	20-Sep-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019 the pet owner reported the following event for a feline of unknown signalment. 11 Sep 2019: The pet owner applied FRONTLINE PLUS CATS (lot number unknown, package unavailable), a dose topically, in between the shoulder blades for the first time. No fleas were seen on the feline at the time of application but the pet owner noted scratching for an unknown period of time. 20 Sep 2019: The feline presented to the clinic where 2 fleas were found and was treated for flea allergy dermatitis with unknown medication. Currently, the pet owner is seeing no fleas on the feline. There is one other feline in the household that was treated with FRONTLINE and has shown no signs of fleas. Both felines spend the entirety of their time inside the home. No further medical information is expected.
25-Sep-2019	UAE; 19US057273; FL; 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	11-Sep-2019	25-Sep-2019	2 Week(s)	D-C	Suspected Adverse Event: On 25 Sep 2019 the clinic staff reported the following event for a canine of unknown signalment. 11 Sep 2019: the pet owner applied FRONTLINE PLUS DOG 45-88 LBS (lot number unknown, package unavailable), half of one vial topically, unknown application site. 25 Sep 2019: The canine developed neurologic issues with unknown symptoms and presented to the clinic. Currently, it is unknown if the patient has received treatment or if the reaction continues. No further medical information is expected.

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						program not respected)					
16-Sep-2019	UAE; 19US057278; -; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Aug-2019	09-Sep-2019	20 Day(s)	D-A	Suspected Adverse Event: On 16 Sep 2019, the pet owner reported the following event for a medium crossbred canine. All other signalments unknown, owner declined to complete report. 20 Aug 2019: 1 vial of FRONTLINE PLUS DOG 22-44 LBS(S60401AZ) was applied to the dog in one area between the shoulder blades. 9 Sep 2019: The dog passed aways from unknown causes The pet owne declined to discuss. There is on other dog in the home see case 19US050152. No further information. UPDATE 04Oct2019: On internal review, it was noted the Date First Received for this case was 16 Sep 2019. No further information.
25-Sep-2019	UAE; 19US057291; AL; U.S.A	**Species:** Canine **Breed:** American Bully **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **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	22-Sep-2019	23-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sept 2019, the owner reported the following event for Chance, 1 year old, 65 pounds*, neutered male, American Bully. 22 July 2019: The dog started on FRONTLINE PLUS on the monthly basis. 8 Sept 2019: The dog was bathed in Dawn. 22 Sept 2019: The most recent vial of FRONTLINE PLUS DOG 45-88 LBS (P63312DR) was applied between the shoulder blades, by the pet owner. It is unknown if fleas were seen at time of application. 23 Sept 2019*: The dog had a large amount of fleas. The owner is not seeing any flea activity in the home. The dog has access to an unknown area outside for bathroom breaks. No further medical information is expected.
25-Sep-2019	UAE; 19US057308; -; 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-Jul-2019*	01-Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, the owner reported the following event for 2 canines with remaining unknown signalment. Feb 2015*: The dogs started receiving FRONTLINE PLUS DOG 45-88 LBS (S62408AX), topically in between the shoulder blades. Jul 2019*: The owner applied 1 dose of FRONTLINE to the dogs. About 3 days later, he was still seeing a small amount of fleas on both dogs. Aug 2019*-Sep 2019*:The owner has been applying the product every month on an unknown date and is still seeing a small to moderate amount of fleas. The dogs are considered an indoor/outdoor; with one dog that only goes outside for occasional walks and potty breaks and the other spending large amounts of time outdoors for playtime. There were a small amount of fleas seen prior to product use. There are 2 other cats in the home that are also on FRONTLINE FOR CATS (product unsubstantiated)(lot unknown) that do have fleas (Please see case 19US057401). The owner has been treating monthly with FRONTLINE since Feb 2015*. No further information at this time.
20-Sep-2019	UAE; 19US057314; WA; U.S.A	**Species:** Canine **Breed:** Papillon **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 9 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	06-Aug-2019	17-Sep-2019	6 Week(s)	D-D	Suspected Adverse Reaction: On 20 Sep 2019, a pet owner reported the following event in Penelope, a 6 year old*, 9 pound, spayed female Papillion mixed breed dog. 6 Jun 2019: The owner started to apply FRONTLINE PLUS DOG 5-22LBS (S62405AX) between the shoulder blades for the first time this year. There is one other dog in the home that recieves FRONTLINE PLUS (see case 19US056255 for a lack of efficacy

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						products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					case for the other dog). The owner uses the product seasonally until October. The most recent application was done on 6 Aug 2019. 17 Sep 2019: Both dogs started itching. 20 Sep 2019: The owner discovered one flea on the other dog, but she has not seen any fleas on Penelope. The home has hardwood floors and a few rugs. The dogs have regular access to their backyard. Urban wildlife is present in the area and back yard; the owner has witnessed raccoons near their fence line. There are no other animals in the home. The home nor the yard have been treated with any pesticides. The owner reports they have used this product before with no issues. No further medical information expected.
25-Sep-2019	UAE; 19US057333; IA; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 8 - 12 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Soft Soap; Johson and Johnson Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Sep-2019	17-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, the pet owner reported the following event for Lucy, a 9 year old, 12 pound, spayed female, Yorkshire terrier Poodle Mix. Stella, a 6 year old, 8 pound, spayed female, Bichon Frise Poodle Mix. 25 Aug 2019*: The owner bathed the animals with Soft Soap and Johnson and Johnson Shampoo. 1 Sep 2019 and 18 Sep 2019*: The patients got their dose of FRONTLINE PLUS DOG 5-22 LBS(S62106AL). Fleas were not seen prior to the use of FRONTLINE. The owner purchased a 6 pack this past purchase, and the animal has used FRONTLINE before but exact amount of years is unknown. Owner did date he is a seasonal user, and uses it usually starting the September of each year until the winter begins. It was applied between the shoulder blades. 17 Sep 2019*: The owner noticed fleas began to appear on the animal. The pets go outside. The pets are showing no skin issues, but are itching from the fleas. There are no fleas in the home, and no fleas on the owner. The patient's current condition is ongoing. There are a total of 2 canines in the household. The owner also mentioned having another animal that was on FRONTLINE when it passed away, see case 19US057333. No further medical information expected.
25-Sep-2019	UAE; 19US057345; -; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 60 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Sep-2019	25-Sep-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, the pet owner reported the following event for a 60 pound, male neutered, Large crossbred. 9 Sep 2019: There were no fleas seen on the dog.1 vial of FRONTLINE PLUS DOG 45-88 LBS(G63701AR) was applied to the dog in one area between the shoulder blades. 25 Sep 2019: The dog was taken to the groomer. The groomer reported to the pet owner that there were "quite a few fleas and 1 tick" on the dog. They bathed him in an unknown flea shampoo to kill and remove all fleas on the dog and now there are no fleas or ticks on the dog. The dog has been on FRONTLINE PLUS for an unknown number of years. The dog goes out for walks daily and potty break in the back yard. There are no fleas in the home. No other dogs. No further information is expected.
25-Sep-2019	UAE; 19US057349; IA; U.S.A	**Species:** Canine **Breed:** Canine (unknown)	2	2	0	**Product used:** FIPRONIL 10%/S	12-Sep-2019	17-Sep-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019 an animal owner reported the following event in 2 female spayed canines. All other signalment unknown.

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		Sex: F **Sex qualifier:** Neutered **Age:** - **Weight:** Unknown				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					12 Sep 2019: The canine were each administered 1 vial of FRONTLINE PLUS DOGS 23-44 LBS (lot, expiration unknown. Package unavailable). 17 Sep 2019: The animal owner saw approximately 3 fleas on each canine. The canines were prescribed CapStar and an unspecified monthly oral flea control. 25 Sep 2019: No fleas after CapStar and oral flea control. The canines have been receiving monthly doses year round without issue. The canines started obedience training in the summer. There are no other pets in the household. The canines have access to outdoors. No further information provided nor expected.
25-Sep-2019	UAE; 19US057353; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown Shampoo; **Route:** unknown **Was the product used ok?:** Unknown to Company	24-Sep-2019	24-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, the pet owner reported the following event for a canine of unknown signalment. 23 Sep 2019*: The owner bathed the animal with an unknown shampoo. 24 Sep 2019: The patient got their dose of FRONTLINE PLUS DOG 23-44 LBS(lot unknown, reporter refused). It is unknown if the animal has had FRONTLINE before. It is unknown where the FRONTLINE was applied. The same day the owner saw flea bites and proceeded to bathe the animal again, after the FRONTLINE application. It is unknown how often the animal goes outside. It is unknown if the animal is having skin issues. It is unknown if fleas are in the house or on the owner. The patient's current condition is unknown. The total number of animals in the house id unknown. The owner was asking if she could dose FRONTLINE again. No further medical information expected.
26-Sep-2019	UAE; 19US057358; -; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 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-Sep-2019	25-Sep-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, the owner reported the following event for Kitty, a 6 year old*, 10 pound*, male , neutered, Domestic Shorthaired . 11 Jul 2019: One vial of the FRONTLINE PLUS CATS (S40601RX) was applied topically in between the shoulder blades by the owner. No fleas seen prior to application. Owner purchased an 8 pack starting in July. 11 Aug 2019: One vial of the FRONTLINE PLUS CATS (S40601RX) was applied topically in between the shoulder blades by the owner. 11 Sep 2019: One vial of the FRONTLINE PLUS CATS (S40601RX) was applied topically in between the shoulder blades by the owner. 25 Sep 2019: A moderate fleas were seen on the cat, this is the first time the owner has noticed fleas on the pet.This is the 3rd dose of the product for the cat. The cat is indoor/outdoor and mostly hangs out around the home when outside. The owner is not seeing fleas within the home. No other pets are in the home and a few stray cats are seen outdoors. No further medical information is expected.
26-Sep-2019	UAE; 19US057361; OH; U.S.A	**Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** U **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** unknown	15-Jun-2019*	16-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, the pet owner reported the following event for a < 20 pound canine of further unknown signalment. Unknown dates: For an unknown number of years, the reporter has applied one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (lot unknown; package unavailable) topically between the dog's shoulder blades, seasonally. The months of application could not

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		Age: - **Weight:** 19 lbs*				oatmeal shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					be confirmed, though typically the canine does not receive FL+ during the winter months. At the unknown times of product application, fleas were never present on the dog. The canine has also been bathed with an unknown oatmeal shampoo via unknown frequency due to an unrelated history of pruritus and undefined skin issues. 12 Jun 2019*: The reporter noticed a small volume of fleas on the canine at which point, the dog had not received any flea control product for 2019. 15 Jun 2019: She began applying one vial of FL+ in the same manner as described above at which time, the canine was pruritic and a small volume of fleas were present. All subsequent FL+ applications follow the same administration protocol and the dates of application are as follows: 15 Jul 2019*, 15 Aug 2019*, and 15 Sep 2019*. A small volume of fleas were observed on the canine at the time of all subsequent FL+ applications. Unknown dates: An unknown duration following FL+ administration, the reporter continued find a small volume of fleas on the dog who also remained pruritic. An unknown date following, the reporter bathed the dog in an unknown oatmeal shampoo to remove any fleas present and to help relieve said symptoms. 26 Sep 2019: Four or five fleas were combed off the canine who continues to be pruritic. Presently, there are no fleas in the home or getting onto the reporter. There is a second dog as well as two cats in the home that are experiencing issues with fleas despite respective FRONTLINE PLUS use. Please see cases 19US057362 and 19US057363. There have been no visiting animals in the home. The
26-Sep-2019	UAE; 19US057362; OH; U.S.A	**Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 23 - 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	15-Jun-2019*	16-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, the pet owner reported the following event for a 23 pound to 40 pound, canine of further unknown signalment. Unknown dates: For an unknown number of years, the reporter has applied one vial of FRONTLINE PLUS DOG 23-44 LBS (FL+) (lot unknown; package unavailable) topically between the dog's shoulder blades, seasonally. The months of application could not be confirmed, though typically the canine does not receive FL+ during the winter months. At the unknown times of product application, fleas were never present on the dog. 12 Jun 2019*: The reporter noticed a small volume of fleas on the canine at which point, the dog had not received any flea control product for 2019. 15 Jun 2019: She began applying one vial of FL+ in the same manner as described above at which time, a small volume of fleas were present on the patient. All subsequent FL+ applications follow the same administration protocol and the dates of application are as follows: 15 Jul 2019*, 15 Aug 2019*, and 15 Sep 2019*. Likewise, a small volume of fleas were observed on the canine at the time of all subsequent FL+ applications. Unknown dates: An unknown duration following FL+ administration, the reporter continued find a small volume of fleas on the dog. 26 Sep 2019: Four or five fleas were combed off the canine this morning and presently, there are no fleas in the home or getting onto the reporter. There is a second dog as well as two cats in the home that are experiencing issues with fleas despite respective FRONTLINE PLUS use. Please see cases 19US057361 and 19US057363.

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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
											There have been no visiting animals in the home. The canine has access to a grassy back yard where there are no wooded areas. The reporter would not provide any further information regarding the external environment, but clarified that she found fleas on both indoor only felines before seeing fleas on either dog. No further medical information expected.
26-Sep-2019	UAE; 19US057363; OH; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 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-Jun-2019*	16-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, the pet owner reported the following event for two < 7 pound felines of further unknown signalment. Unknown dates: For an unknown number of years, the reporter has applied one vial of FRONTLINE PLUS CAT (FL+) (lot unknown; package unavailable) topically between each cat's shoulder blades, seasonally. The months of application could not be confirmed, though typically the felines do not receive FL+ during the winter months. At the unknown times of product application, fleas were never present either feline who have always remained strictly indoors. Jun 2019* (unknown date): The reporter noticed a small volume of fleas on each feline and neither cat had received any flea control product in 2019. 15 Jun 2019: The reporter began applying one vial of FL+ in the same manner as described above at on each cat at which time, a small volume of fleas were present on both felines. All subsequent FL+ applications follow the same administration protocol and the dates of application are as follows: 15 Jul 2019*, 15 Aug 2019*, and 15 Sep 2019*. Likewise, a small volume of fleas were observed on each feline at the time of all subsequent FL+ applications. Unknown dates: An unknown duration following FL+ administration, the reporter continued find a small volume of fleas on each cat. 26 Sep 2019: Four or five fleas were combed off of each feline this morning and presently, there are no fleas in the home or getting onto the reporter. There are two dogs in the home that are experiencing issues with fleas despite respective FRONTLINE PLUS use. Please see cases 19US057361 and 19US057362. There have been no visiting animals in the home. Although neither cat has access to the outdoors, the yard where both dogs have access to is grassy and there are no wooded areas. The reporter would not provide any further information regarding the external environment, but clarified that she found fleas on both felines before seeing fleas on
22-Sep-2019	UAE; 19US057376; -; U.S.A	**Species:** Canine **Breed:** Rat Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 10.000 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 /	27-Aug-2018*	01-Sep-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Sep 2019, a pet owner reported the following event in Cricket, a 4 year old, 10 pound, spayed female, Rat Terrier mixed breed canine. 27 Jun 2019, 28 Jul 2019, and 27 Aug 2019: The dog received the most recent doses of FRONTLINE PLUS S (S60341AL, 31 Jan 2021, foreign product) between the shoulder blades. There are 4 other dogs on the property that all receive FRONTLINE PLUS. The owner uses FRONTLINE PLUS year round on all of the dogs. 1 Sep 2019*: The owner discovered the dog had fleas present on her. 12 Sep 2019: The dog received another dose of FRONTLINE PLUS between the shoulder blades. 13 Sep 2019*: The owner continued to see fleas on the pet. The owner is being bitten by fleas in the home. 2 of the other dogs also have fleas. Cricket is mainly indoor, but has access to the yard.

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						vaccination program not respected)					One other dog is indoor and has fleas (see case 19US057407) as well as one of the outside dogs (also case 19US057407). The last 2 outside dogs have not had fleas discovered on them. The outside dogs have access to many acres of land, but the owner says she keeps wildlife to a minimum with the dogs and trapping. The acreage has a lot of trees and foliage. There are several barn cats on the property that have not been treated with flea prevention ever. The house is being vacuumed regularly, but the owner has not treated the yard with pesticides. The house was treated with an unknown pesticide at an unknown date. No further medical information expected. UPDATE 07 Oct 2019: The 'no more information expected' box was checked.
26-Sep-2019	UAE; 19US057378; IL; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 34 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Sep-2019*	26-Sep-2019	3 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, the pet owner reported the following event for a 34 pound, 1 year old, female spayed German Shepherd Dog. 5 Sep 2019*: There were no fleas seen on the dog. 1 vial of FRONTLINE PLUS DOG 23-44 LBS(S60308AL) was applied to the dog in one area between the shoulder blades. 26 Sep 2019: There are 1-2 fleas on the dog. The dog goes out for potty breaks and recreation, and to the dog park daily. There are no fleas in the home. The owner has been treating with FRONTLINE since 2018. No further information.
26-Sep-2019	UAE; 19US057382; NH; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **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	22-Sep-2019*	26-Sep-2019*	4 Day(s)	D-D	Suspected Adverse Event: On 26 Sep 2019, the pet owner reported the following event for 1 feline, 16 pounds*, male, all other signalments unknown. 22 Sep 2019*: The owner purchased FRONTLINE PLUS CATS (R41105AW) from Ebay and applied the contents of one vial to the skin between the shoulder blades. 26 Sep 2019*: The owner reported the feline vomiting, lethargic, flaky skin. She noticed the pipette labeled for dogs 45-88 pounds. The feline has history of receiving FRONTLINE PLUS CATS without issue. No further medical information expected. Product quality: On 26 Sep 2019, the pet owner reported the following issue with a card of FRONTLINE PLUS CATS (R41105AW). After first application of product, owner noticed that box and blister said FRONTLINE PLUS CATS and the pipette stated FRONTLINE PLUS DOG 45-88 lbs. The owner read R41105AW on the box, R41105 on the blister cavity, and R405 on the pipette. No further information expected. 23-OCT-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot# R41105AW, expiry . Case investigated by USA - Duluth. Final complaint evaluation An investigation launched in regards to a recent influx of reports of the defect: packaging mix-up for Frontline Plus for Cats. The Frontline Plus for Cats blister cavities contained a pipette labeled Frontline Plus for Dogs 45-88 lbs. Packaging and pipette content lab analysis of the complaint sample for PRID 389268, revealed the packaging and the pipette liquid contents to be counterfeit with no evidence of BIAH active ingredients. The pipette content lab analysis in complaint 389268,

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											is a reference sample for all cases received with the lot number R41105AW in which the packaging components of the photos/samples received are consistent with the same counterfeit discrepancies as the packaging for PRID 389268. Based on the above information, a simplified approach and a separate investigation summary is not required for closure. These cases are justified
25-Sep-2019	UAE; 19US057401; -; U.S.A	**Species:** Feline **Breed:** - **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-Jul-2019*	01-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 25 Sep 2019, the owner reported the following event for 2 felines with remaining unknown signalment. Feb 2015*: The dogs started receiving FRONTLINE PLUS CATS (Lot Unknown, Reporter Not Queried), topically in between the shoulder blades. Jul 2019*: The owner applied 1 dose of FRONTLINE to the cats. About 3 days later, he was still seeing a small amount of fleas on both cats. Aug 2019*-Sep 2019*:The owner has been applying the product every month on an unknown date and is still seeing a small to moderate amount of fleas. The cats are considered an indoor. There were a small amount of fleas seen prior to product use. There are 2 other dogs in the home that are also on FRONTLINE PLUS FOR DOGS 45-88(S62408AX) that do have fleas (Please see case 19US057308. The owner has been treating monthly with FRONTLINE since Feb 2015*. No further information at this time.
22-Sep-2019	UAE; 19US057407; -; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 55 - 80 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	27-Aug-2018*	01-Sep-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 22 Sep 2019, a pet owner reported the following event in 2 canines, Megan, a 55 pound, 5 year old, spayed female German Shepherd Dog, and Dandy, a 6 year old, 80 pound, spayed female, Doberman canine. 27 Jun 2019, 28 Jul 2019, and 27 Aug 2019: The dogs received the most recent doses of FRONTLINE PLUS DOG L (R60906AR, 30 Mar 2021, Australian product and S62009AX, 31 Jul 2021 foreign product) between the shoulder blades. There are 3 other dogs on the property that all receive FRONTLINE PLUS. The owner uses FRONTLINE PLUS year round on all of the dogs. 1 Sep 2019*: The owner discovered the dogs had fleas present on them. 12 Sep 2019: The dogs received another dose of FRONTLINE PLUS between the shoulder blades. 13 Sep 2019*: The owner continued to see fleas on the dogs. The owner is being bitten by fleas in the home. Megan is mainly indoor but still has access to the yard, Dandy is an outdoor only dog. One other dog is indoor and has fleas (see case 19US057376). The last 2 outside dogs have not had fleas discovered on them. The outside dogs have access to many acres of land, but the owner says she keeps wildlife to a minimum with the dogs and trapping. The acreage has a lot of trees and foliage. There are several barn cats on the property that have not been treated with flea prevention ever. The house is being vacuumed regularly, but the owner has not treated the yard with pesticides. The house was treated with an unknown pesticide at an unknown date. No further medical information expected.
11-Sep-2019	UAE; 19US057411; IL; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE	01-Mar-2019*	04-Sep-2019	4 Week(s) 6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Sep 2019, the animal owner reported the following event for Bella, a 4 year old*, 18.0 pound*, spayed female Shih Tzu Poodle Mix. Mar 2019* through Aug 2019*: The owner did not notice fleas on

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		Neutered **Age:** 4.00 Year(s) **Weight:** 18.0 lbs				9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					the canine or off of the canine in the household. She received FRONTLINE PLUS DOG 5-22 LBS (lot unknown) (package unavailable) one dose topically between the shoulders. 15 Jul 2019*: The dog was pet sat by a friend with two felines that had fleas in a different household. 16 Jul 2019*: The owner did not see any fleas, but felt that the her fur felt abnormally dirty. She bathed her in a pet approved shampoo. 29 Aug 2019, 31 Aug 2019, and 02 Sep 2019: She was bathed in Dawn dish soap every other day. 03 Sep 2019: The owner noticed a small amount of fleas. She presented to the veterinary clinic. She was bathed in Dawn dish soap. The owner applied FRONTLINE GOLD DOG 5-22 LBS (lot unknown) (package unavailable) one dose applied topically. The owner has continued to notice fleas on the canine, but not off of the canine within the household (see case 19US054281). Her current condition is ongoing. The canine does frequent the grass covered yard. The owner has continued to bathe the canine every other day in Dawn dish soap. She has previously received FRONTLINE PLUS DOG 5-22 LBS monthly, seasonally for an unknown length of time with no previous adverse effects. No further information expected.
26-Sep-2019	UAE; 19US057451; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Sep-2019*	26-Sep-2019	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, a pet owner reported the following event for a canine of unknown signalment. Unknown Date: The owner applied FRONTLINE PLUS DOG 23-44 LBS (lot unknown, package unavailable) and fleas were present. 26 Sep 2019: The owner is still seeing fleas. All other details are unknown. No further medical information expected.
26-Sep-2019	UAE; 19US057473; WI; 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	01-Apr-2019*	19-Sep-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019 the pet owner reported the following event for 4 felines of unknown further signalment. 1 Apr 2019*: All 4 felines were started on FRONTLINE PLUS CATS (lot number unknown, package unavailable), 1 vial topically, in between the shoulder blades, once monthly. The pet owner claimed she saw no fleas on the felines or inside the home at the time of application. 19 Sep 2019: The pet owner reported she began seeing a small amount of fleas on all 4 felines. Currently, the pet owner is seeing a large amount of fleas on all 4 felines and inside the home. All 4 felines spend equal amounts of time inside and outside the home and it is unknown what outside environment they have access to. No further medical information is expected.
26-Sep-2019	UAE; 19US057482; CT; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products**	01-Sep-2019*	26-Sep-2019	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, the pet owner reported the following event for 3 cats of unknown signalment. 01 Aug 2018*: The pet owner began applying monthly the contents of 1 vial of FRONTLINE PLUS CATS (lot unknown/package unavailable) to the skin between the shoulder blades for the first time.

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		Age: - **Weight:** Unknown				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					01 Sep 2019*: The owner applied the most recent dose. 26 Sep 2019: The owner reports seeing unknown amount of live fleas on pets. There are no additional pets in the household. The cats are indoors only. There is urban wildlife seen near the home. The owner has treated the household with Knock Out Spray on an unknown date. None of the cats have had a bath. No further medical information expected.
26-Sep-2019	UAE; 19US057485; -; 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	16-Sep-2019*	25-Sep-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, the owner reported the following event for 2 felines, all other signalment unknown. 16 Sep 2019*: One vial of FRONTLINE PLUS CATS (Unknown lot, package unavailable) was applied topically in between the pet's shoulder blades by the owner. Purchased unknown amount of doses in September. 25 Sep 2019: The owner noticed a small amount of fleas crawling on the cats' face and body. The owner has not presented the pets to the clinic. The cats are indoor only. No fleas have been seen within the home.This is the first application of the product. No further medical information expected.
26-Sep-2019	UAE; 19US057495; 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	10-Jul-2019*	12-Sep-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sept 2019, the pet owner reported the following event for 3 canines of unknown signalment. 10 Jul 2019*, 7 Aug 2019*, and 9 Sept 2019: The pet owner applied a dose of FRONTLINE PLUS DOG (unsubstantiated) (lot and expiration unknown, package unavailable) to each of the dogs. 12 Sept 2019: The pet owner started to find fleas on the dogs. There are 3 cats in the home who are treated with FRONTINE PLUS CATS (lot unknown, not queried) and they do not have fleas. All of the pets go outside where there is wildlife. There are no fleas in the home and the dogs are bathed a few times a month with a flea shampoo. The home has been treated. The pets are treated monthly year round. No further medical information expected.
26-Sep-2019	UAE; 19US057497; NC; U.S.A	**Species:** Canine **Breed:** Dalmatian **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 47 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown flea spray; Unknown shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	25-Aug-2019	27-Aug-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019 a pet owner reported the following event for a 47 pound, female Dalmatian of unknown other signalment. 25 Aug 2019*: Owner applied FRONTLINE PLUS DOG 45-88 LBS (R62001) to the skin between the animal's shoulder blades for the first time. Unknown date: The dog presented to the clinic and was started on an unknown prescription flea product. Owner called to say he was seeing fleas and was unhappy with the product. It is unknown when he saw them or how many fleas the pet owner is seeing. The outdoor and indoor environment is unknown. There dog was bathed with an unknown shampoo on an unknown date and the owner applied an unknown fleas spray to the dog on an unknown date. There is one other dog in the home who is not on FRONTLINE, but owner is only bathing that dog and using fleas spray. The owner declined to make a report. No further medical information is expected.
26-Sep-2019	UAE; 19US057499; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown)	3	3	0	**Product used:** FIPRONIL 10%/S	25-Sep-2019*	26-Sep-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 26 Sep 2019, the pet owner reported the following event for 3 canines of unknown signalment Unknown date: The pets began receiving FRONTLINE PLUS DOG

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		Sex: U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					(Lot unknown) (package unavailable) (product unsubstantiated). The pets are treated monthly. Unknown date: The pets have been experiencing itching for an unknown amount of time. No fleas have been seen. The pets have presented to the veterinarian. Physical exam and skin scraps have been performed. No evidence of any organisms that could be causing the itching. Owner declined to provide any additional information. No further medical information expected.
26-Sep-2019	UAE; 19US057514; IL; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Month(s) **Weight:** 35 lbs	2	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	14-Aug-2019	01-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, the pet owner reported the following event for Feta, a 10 month old, neutered male, 35 pound, Labrador Retriever. 14 Aug 2019: The dog began receiving FRONTLINE PLUS DOG 23-44 LBS (S61727AL) monthly with 3 pack purchased from Wal-Mart. The product is applied directly on the skin between the shoulder blades. This is the first time the pet received FRONTLINE PLUS. It is unknown if fleas were seen prior to product application. 14 Sep 2019: The most recent date of application. Sep 2019*: The owner began noticing fleas. The dog has access a fenced in yard, with one tree in the yard. The dog does go to a BMX track area once a week. The dog does not go on walks, dog parks, or to the groomer. No treatments have been provided at home. The dog's current condition is ongoing. There is a cat in the home, who is also being treated with FRONTLINE monthly. No further medical information expected.
26-Sep-2019	UAE; 19US057520; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	20-Sep-2019	21-Sep-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 26 Sep 2019, the following event was reported by the pet owner for a 5 year old, male feline, with unknown signalment. Unknown Date: The pet owner first noticed fleas on the cat, at which time he was scratching. At that same time, the pet owner was finding scabs on the cat, which she attributes to the presence of fleas, because the cat has a history of flea allergy dermatitis. 20 Sep 2019: The owner applied an unknown amount of FRONTLINE PLUS CATS (lot unknown; reporter not queried), to an unknown location on the cat. Unknown Date: An unknown duration following the FRONTLINE PLUS CATS application, the pet owner noticed increased itching, an increased amount of scabs on the cat and unknown hair loss of which the reporter did not further describe. Presently, the symptoms are ongoing. Fleas are still present on the cat. No further information could be obtained because the reporter was only calling to ask questions, and was not intending to report the adverse event. No further medical information expected.
26-Sep-2019	UAE; 19US057521; CA; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** Neutered **Age:** 1.50 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	13-Sep-2019	24-Sep-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 26 Sep 2019, the owner reported the following event for Prince, a 8 pound, male neutered, 1.5 year old, Chihuahua. 13 Sep 2019: One vial of the FRONTLINE PLUS DOG 5-22 LBS (S61902AL) was applied topically in between the shoulder blades by the owner. 24 Sep 2019: The owner noticed a large amount of fleas were seen on the dog. Owner purchased 6 pack on the 8th of September. 25 Sep 2019: The owner took the dog to the vet and was given

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						Was the product used ok?: Yes					Accugard Chew. 26 Sep 2019: The dog recovered. The dog is indoor mostly and is walked on a leash for potty breaks and recreation. Fleas are seen within the home and the home is treated for fleas. No wildlife is not seen within the area. This is the first application for dog. No further medical information is expected
26-Sep-2019	UAE; 19US057554; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	01-Sep-2017*	26-Sep-2019	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019 the pet owner reported the following event for a canine of unknown signalment. Unknown date 2017: Started on FRONTLINE PLUS DOG 5-22 LBS (lot number unknown, package unavailable) (product unsubstantiated), 1 dose topically, in between the shoulder blades, once monthly. 1 Sep 2019*: The most recent dose was applied. 26 Sep 2019: The pet owner reported that she started seeing an unknown number of fleas on the canine and none inside the home. It is unknown where the canine spends the majority of the time or what outside areas the pet has access to. There are no other pets in the household. No further medical information is expected.
26-Sep-2019	UAE; 19US057573; MI; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 10.000 - 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	05-Aug-2019	10-Sep-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, the pet owner reported the following event for Skid, a 10 year old*, neutered male, 10-11 pound*, Domestic Longhair. Unknown date: The cat began receiving FRONTLINE PLUS CATS monthly as seasonal use. 5 Aug 2019: The cat received FRONTLINE PLUS CATS (S40815AW) monthly from a 6 pack. The product was applied directly on the skin between the shoulder blades. 6 Aug 2019: Pet owner reports finding a tick on the pet. 5 Sep 2019: The most recent date of application. 10 Sep 2019: The owner is still noticing ticks. The cat does have access to outside, rural area, with urban wildlife present. The cat did not present to the veterinary clinic. No treatments have been provided at home. The cat's current condition is ongoing. There are no other pets in the household. The client took the tick to the veterinary clinic and was identified as a black legged deer tick. No further medical information expected.
26-Sep-2019	UAE; 19US057578; OH; U.S.A	**Species:** Feline **Breed:** Feline various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** unknown Hartz flea treatment; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Jun-2019	01-Mar-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, the pet owner reported the following event for 3 cats with unknown signalment. Jan 2019*: The cats began receiving FRONTLINE PLUS CATS (S40210BW) monthly with 3 vials purchased on an unknown date from Walmart. The product is applied monthly directly on the skin between the shoulder blades. Fleas were not seen prior to product application. 1 Mar 2019*: The pet owner began seeing fleas. May 2019*: The only applied one dose of an unknown Hartz flea treatment. 15 Jun 2019: The monthly dose of FRONTLINE PLUS was applied. 13 Jul 2019: The monthly dose was applied. 14 Aug 2019: The monthly dose was applied. 12 Sep 2019: The monthly dose was applied. 19 Sep 2019: One of the cats was bathed in Lemon Dawn. 26 Sep 2019: The owner is still noticing moderate fleas. 1 of the cats is indoor/outdoor and the other 2 cats are indoors only. The cats have not presented to the veterinary clinic. No other

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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
											treatment has been provided at home. The cats' current condition is ongoing. There a total of 3 felines and no other animals in the household.There were 6 kittens in the home that passed away at around 4 weeks of age* on unknown dates. Those kittens were not treated with FRONTLINE PLUS. The pet owner did treat the yard and inside the home with an unknown industrial strength pesticide. No further medical information expected.
26-Sep-2019	UAE; 19US057587; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2019*	22-Sep-2019*	3 Week(s)	D-A	Suspected Adverse Event: On 26 Sep 2019 a pet owner reported the following event for a male dog of unknown signalment. Unknown date: The dog started receiving FRONTLINE PLUS DOG 89-132 LBS (lot unknown, reporter not queried). Unknown date: Dog died or was euthanized due to age related issues. No further details are known. The pet owner was not calling to report this event, but to ask about using the product off label with her smaller dog. Confirmed with the pet owner that the dog's death was not related to the FRONTLINE. No further medical information expected.
26-Sep-2019	UAE; 19US057613; TN; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **Sex:** X **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	18-Sep-2018*	22-Sep-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, the pet owner reported the following event for 3 retrievers of unknown signalment. Sep 2018*: The pets began receiving monthly FRONTLINE PLUS DOG 45-88 LBS (lot unknown) (package unavailable), applied 1 vial topically between the shoulder blades for the first time. 18 Sep 2019: The most recent dose was applied to all pets, FRONTLINE PLUS 45-88 LBS (S63106AX) 22 Sep 2019*: The owner noticed a small amount of fleas on the pets. The owner has not been noticing fleas off of the pet inside the home. There a total of 3 canines in the household. They are indoor/outdoor. The yard is fenced. One pet has presented to the veterinarian for the itching, received a cortisone shot. No further medical information expected. UPDATE 09 Oct 2019: Patient numbers changed to reflect only 2 dogs. The third dog treated, which was treated with cortisone, is reported separately in case 19US059163.
26-Sep-2019	UAE; 19US057625; PA; U.S.A	**Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** M **Sex qualifier:** Neutered **Age:** 8.50 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	15-May-2019*	26-Sep-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sept 2019, the pet owner reported the following event for Gibbs, an 8.5 mouth old 16 pound male neutered Jack Russell Terrier. 19 Sept 2019: A dose of FRONTLINE PLUS DOG 5-22 LBS (S61902AL) was applied to the dog. The pet owner has been applying monthly doses since 15 May 2019*. Jun 2019*: The pet owner started seeing fleas on and off in the home and on the dog. 26 Sept 2019: The pet owner is still seeing fleas. The home was treated with Diatomaceous Earth and vacuumed. The dog goes out side where there are some trees and wildlife. There are no other pets in the home. The dog is bathed about once a month with Burt's Bees dog shampoo. No further medical information expected.

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26-Sep-2019	UAE; 19US057630; CA; U.S.A	**Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 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	08-May-2019*	12-Sep-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy: On 26 Sep 2019, a pet owner reported the following event for Shiro, a 12 year old, 8.5 pound, neutered male, Domestic medium hair feline. 8 May 2019*: The cat received FRONTLINE PLUS CATS (S40404AW) between the shoulder blades for the first time this year. The pet owner applies this monthly. Prior to this the cat was receiving another unknown kind of flea prevention. The owner is unsure if this is the first time the cat has received FRONTLINE PLUS in its life. The owner uses flea prevention year round. 8 Sep 2019: The cat received its most recent application of FRONTLINE PLUS. 12 Sep 2019*: The owner discovered the cat had fleas. She reported picking at least 8 off of him at a time. The cat has access to the yard. The yard has gravel, large rocks, and grass present. The home is in a neighborhood. It is unknown if there is urban wildlife present. There are no other animals in the home. The owner is not being bitten at this time. No further medical information expected.
26-Sep-2019	UAE; 19US057634; VA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 125 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	05-Sep-2019	19-Sep-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sept 2019, the owner reported the following event for a 125 pound, 8 year old, male canine (all other signalment unknown) Unknown date: The owner purchased 12 doses of FRONTLINE PLUS DOG 89-132 LBS (lot unknown, package unavailable). 5 Sept 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown, package unavailable) was applied between the shoulder blades. 19 Sept 2019: The owner started to notice fleas on the pet for the first time. The owner treated the home. No fleas were noted in the household. 20 Sept 2019: The owner bathed the pet with flea shampoo and adminstered Benadryl. 26 Sept 2019: The issue is still ongoing. The dog has access to 1 acre of land. the dog has received the product year round since 2011*. There are no other pets in the household. No further medical information is expected.
26-Sep-2019	UAE; 19US057636; NY; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **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	21-Sep-2019	21-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim and adverse event: On 26 Sep 2019, the pet owner reported the following event for Louie, a 6 year old*, neutered male, feline, with rest of signalment unknown. Unknown date: The cat has been scratching. 21 Sep 2019: The cat began receiving FRONTLINE PLUS CATS (S40404AW) from. The product was applied directly on the skin between the shoulder blades. It is unknown if fleas were seen prior to product application. After application, the cat began experiencing lethargy, recovered about 1-2 days after product application. 26 Sep 2019: The owner is noticing flea dirt. The cat is still scratching. The cat's current condition is ongoing. There a total of two felines and one canine in the household. No further medical information expected.
27-Sep-2019	UAE; 19US057649; MI; 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:** Dawn;	15-Sep-2019	17-Sep-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Sep 2019, the pet owner reported the following event for a 12 to 13 pound*. 4 year old, male neutered, small crossbred. Mar 2019*: The dog was not having an issue with fleas. The owner began seasonal monthly applications of FRONTLINE PLUS DOG 5-22 (S61920AL). 15 Sep 2019: There was 1 flea on the dog. The owner applied 1

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		Age: 4.00 Year(s) **Weight:** 12 - 13 lbs				**Route:** Topical / Cutaneous **Was the product used ok?:** Yes					dose of FRONTLINE in one area between the shoulder blades. 17 Sep 2019* There was 1 flea on the dog. The owner bathed the dog in Dawn. 25 Sep 2019: There was 1 flea on the dog. The owner bathed the dog in Dawn. 27 Sep 2019: The owner reports she has seen 1 flea on the dog daily since the application. The dog goes out for potty breaks and recreation in an open yard where urban wildlife present. There are no fleas in the home. The owner treats seasonally. No further information.
25-Sep-2019	UAE; 19US057658; IA; U.S.A	**Species:** Canine **Breed:** Basset Hound **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2019*	02-Jan-2019*	1 Day(s)	D-A	Suspected Adverse Event: On 25 Sep 2019, the pet owner reported the following event for Basset Hound of further unknown signalment. 2018*: The patient got their dose of FRONTLINE PLUS DOG (Unsubstantiated)(lot and expiration unknown, report refused). It is unknown where the dose was applied on the animal. 2018*: The animal was diagnosed with cancer, and passed away an unknown time after. The owner refused further inquiry. The owner had originally reported a lack of efficacy for his current animals , see case 19US057333. No further medical information expected.
27-Sep-2019	UAE; 19US057668; TX; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **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?:** No (Treatment / vaccination program not respected)	08-Sep-2019*	09-Sep-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 27 Sep 2019, the pet owner reported the following event for JJ, a 9 years old, 29 pound male canine of unknown breed. 8 Jul 2019*: The pet began receiving monthly FRONTLINE PLUS DOG 23-44 LBS (S61701AL), applied 1 vial topically on the back of the neck. 8 Sep 2019*: The pet went to the groomer and later that day the most recent monthly dose was applied. 9 Sep 2019*: The pet began experiencing an increase in itching that owner suspects is due to fleas. The owner has not seen any fleas. 22 Sep 2019: The owner applied an additional dose. 23 Sep 2019*: The pet continues to scratch. The pet has not presented to the veterinarian. No further medical information expected.
27-Sep-2019	UAE; 19US057670; FL; U.S.A	**Species:** Canine **Breed:** Griffon (Brussels) **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 14 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** SC-subcutaneous **Was the product used ok?:** Yes	07-Sep-2014	27-Sep-2019	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 27 Sep 2019, a pet owner reported the following event for Sparky, a 14 pound, 14 year old, neutered male, Brussels Griffon. 7 Sep 2014: The pet owner was seeing a large amount of fleas on her dog and outside of the home. The owner purchased and applied for the first time 1 dose of FRONTLINE PLUS DOG 5-22 LBS (S61902AL), topically between the shoulder blades. The dog is indoor/outdoor. He has access to a backyard with grass. He spends the majority of his time indoors. There are no other animals in the home. 7 Oct 2014: The owner noticed that the dog had a large amount of fleas on him and outside of the home. 7 Sep 2019: The pet owner applied the most recent dose of FRONTLINE to the dog and is still seeing a large amount of fleas on her dog and outside of the home. The owner uses the FRONTLINE PLUS year round since 2014.

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											She will have a professional exterminator come to spray the home this week. The issue is ongoing. No further medical information expected.
20-Sep-2019	UAE; 19US057691; DC; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **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	18-Aug-2017*	13-Sep-2019	26 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 20 Sept 2019, the owner reported the following event for a 36 pound canine (all other signalments unknown). 18 Aug 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown, package unavailable) was applied between the shoulder blades. 13 Sept 2019: The owner started to notice fleas for the first time. 18 Sept 2019: Another vial was applied. 20 Sept 2019: The issue is still ongoing. The dog has access to a fenced in yard. The dog has been receiving the product year round since 2017 with no issue. There are 3 other dog in the home using different weight categories and experiencing an issue (see case 19US056247, and 19US057692). No further medical information is expected.
27-Sep-2019	UAE; 19US057720; IL; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 80 - 82 lbs*	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	01-Apr-2019*	01-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 27 Sep 2019, the animal owner reported the following event for two canines, 80.0 to 82.0 pounds*, otherwise unknown signalment. Apr 2019*: The owner had not noticed fleas on the canines. The owner had not noticed fleas off of the canines inside of the home. They received FRONTLINE PLUS DOG 89-132 LBS (S62311AX) one dose per canine applied topically between the shoulders for the first time this year monthly. Jun 2019*: They began experiencing pruritus. The owner noticed an unknown amount of fleas on the canines. The owner has not been noticing fleas off of the canines inside of the household. The canines frequent the unknown type property. They frequent parks and take walks. They have not presented to the veterinary clinic. No treatments have been performed. 13 Sep 2019*: The most recent date of application. The owner does bathe the canines at an unknown frequency with an unknown human shampoo. There are no other pets in the household. Another adverse event was reported (see case 19US057752). No further medical information expected.
17-Sep-2019	UAE; 19US057733; TN; U.S.A	**Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 12 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)	09-Jun-2019	09-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: : On 17 Sep 2019, the following event was reported to Safety Call International (SCI) by the pet owner for the following event for Louise, 8 year old*, 12 pound, spayed female Domestic Longhair. 9 June 2019: The pet owner applied 1 vial of FRONTLINE PLUS DOG (45-88LBS)(Lot unknown, package unavailale) that was contained in a 3 pack of FRONTLINE PLUS CATS (R41105AW) (see case19US055716 for product quality report) topically between the shoulder blades of the pet. The pet started to vocalize and roll on the ground 3 hours* after the application of the product. The pet owner attempted to wipe the product off the pet and the pet stopped vocalizing and rolling. 17 Sep 2019*: The cat currently has dandruff along her back at the base of her tail (not at the application site). It is unknow when this started. The pets environment is unknown. It is unknown if the pet is bathed. The pet was heathy at the time of the application. It is unknown if the pet has a history of vaccine reactions. It is unknown if the pet was on any other medications at the time of application. No further medical information expected.

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27-Sep-2019	UAE; 19US057747; MO; U.S.A	**Species:** Canine **Breed:** Australian Shepherd **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Month(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	20-Aug-2019	20-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 27 Sep 2019 the pet owner reported the following event for Penny, a 10 month (28 Nov 2018), 17 pound*, spayed female, Australian Shepherd. Unknown Date: The owner noticed a large amount of ticks on the pet. 20 Aug 2019: The pet owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS (S61412AL) topically between the shoulder blades for the first time. 20 Sep 2019: The owner noticed an unknown amount of fleas and ticks on the dog. 21 Sep 2019: The pet owner applied FRONTLINE PLUS DOG. 27 Sep 2019: The pet owner continues to see fleas and ticks on the pet. The pet has access to a yard with grass and it is unknown if wildlife is present. The pet is not bathed. There are no other pets in the home. The owner is not seeing fleas in the home. No further medical information expected.
27-Sep-2019	UAE; 19US057752; IL; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** Unknown	1	1	1	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Jan-2019*	01-Jan-2019*	0 Day(s)	D-A	Suspected Adverse Event: On 27 Sep 2019, the pet owner reported the following event for a 15 year old* canine of unknown signalment. Unknown Date: The pet received FRONTLINE PLUS DOG 89-132 LBS (lot unknown) (reporter not queried), unknown volume via an unknown route, at an unknown location, monthly, seasonally for unknown length of time. It is unknown experienced any clinical signs. The pet expired on an unknown date. The owner called to report a lack of efficacy case, see case 19US057720. This is the extent of information known. No further medical information expected.
27-Sep-2019	UAE; 19US057762; IN; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 50.0 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	27-Aug-2019	13-Sep-2019*	17 Day(s)	D-D	Suspected Adverse Event: On 27 Sep 2019, the pet owner reported the following event for Maddie, a 50 pounds*, 6 year old*, spayed female crossbred canine. 27 Aug 2019: The most recent dose of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) (reporter not queried) was applied topically in an unknown location on the dog. Unknown date: The dog began experiencing a hot spot on the back of an unknown leg. She presented to the veterinarian on an unknown date, and was prescribed an unknown steroid cream and is also fed grain free food. Her current condition is ongoing. The dog has a history of experiencing hot spots. The dog has been on FRONTLINE PLUS DOG 45-88 LBS monthly since she was a puppy, 6 years ago*. No further medical information is expected.
27-Sep-2019	UAE; 19US057770; FL; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Mixed **Age:** 7.00 Year(s) **Weight:** 25 - 100 lbs*	5	5	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used**	05-Jan-2019*	15-Jan-2019*	N/A	D-D	Suspected Lack of Efficacy: On 27 Sep 2019, a pet owner reported the following event for 5 dogs: Little Shit, a 10 year old, 25 pound, male neutered, Yorkshire terrier canine, Dozer, an 11 year old, 100 pound, Pit Bull and Boxer mixed breed canine, Malcolm, a 7 year old, 75 pound, intact male, Bloodhound canine, Malacai, a 7 year old*, 60 pound, intact female, Bloodhound canine, and Grizley, a 7 year old*, 50 pound, male, Large mixed breed canine with further unknown signalment. 5 Jan 2019*: The dogs received FRONTLINE PLUS DOGS (unknown size, lot unknown, package unavailable, product unsubstantiated) in an unknown location for the first time this year.

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						ok?: Unknown to Company					The pet owner applies flea prevention monthly around the 5th of each month. There are 6 outdoor cats who also receive FRONTLINE PLUS monthly (see case 19US057854). 15 Jan 2019*: The pet owner discovered all of the dogs had fleas. They were all itchy because of the fleas. 15 Feb 2019*: The owner started giving weekly baths to all of the dogs with an unknown shampoo. The dogs receive the baths every week on an unknown date. 27 Sep 2019: The pet owner has seen fleas all summer long, they have not gone away on any of the animals. 5 of the 6 dogs live outside only and all of the cats live outside. There is urban wildlife present on the acre of property. The property is mostly sand, dirt, and some grass. The house is treated weekly for fleas with an unknown pesticide. The owner was being bitten by fleas prior to the pesticide being used in the house on an unknown date. The owner has thrown away all of the packaging for all of the FRONTLINE PLUS and has no record of what sizes each dog uses. No further medical information expected.
27-Sep-2019	UAE; 19US057772; 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	08-Apr-2019*	09-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Sept 2019, the owner reported the following event for a canine (all other signalments unknown). Apr 2019*: The dog started on FRONTLINE PLUS on a monthly basis. Aug 2019*: The dog was exposed to a flea life cycle. 8 Sept 2019: The most recent vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, reported not queried) was applied between the shoulder blades, by the pet owner. 9 Sept 2019*: The dog had a moderate amount of fleas. The dog was bathed in a Sentry shampoo on a unknown date. The owner also used an unknown spray on the dog. The owner is not seeing any flea activity in household. The dog has access to an unknown area for bathroom breaks. No further medical information is expected.
27-Sep-2019	UAE; 19US057792; MO; U.S.A	**Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** - **Age:** 2.00 Year(s) **Weight:** 10 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 (Treatment / vaccination program not respected)	01-Mar-2019*	19-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 27 Sep 2019 The pet owner reported the following event for Roger a 2 year old*, 10 pound*, intact male, Maltese. 1 Mar 2019* - 1 Aug 2019: The pet owner applied one vial of FRONTLINE PLUS DOG 5-22 LBS(lot unknown, package unavailable) topically between the shoulder blades to the pet. The pet owner uses the product seasonally. 5 Sep 2019: The monthly dose of FRONTLINE PLUS was applied. 19 Sep 2019: The owner noticed 10 fleas on the pet and topically applied one vial of FRONTLINE PLUS DOG to the pet. 25 Sep 2019: The owner continues to notice fleas on the pet and bathed in Dawn dish soap. The pet owner then applied another dose of FRONTLINE PLUS DOG. 26 Sep 2019: The pet owner brought the pet to the veterinarian and they prescribed an unknown amount and dose of NEXGARD (11.3) (lot unknown, product unsubstantiated). It is unknown if fleas are being seen after administration of NEXGARD. The pet is leash walked outside in a grass yard and urban wildlife is present. There are no other pets in the home. The pet owner is not seeing fleas in the home. The pet has been receiving FRONTLINE PLUS DOG 5-22 LB seasonally since March 2017* with no reported lack of efficacy. The medical history of the pet is unknown. No further medical information expected.

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27-Sep-2019	UAE; 19US057844; 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?:** No (Treatment / vaccination program not respected)	13-Sep-2019*	27-Sep-2019*	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Sep 2019, the pet owner called and reported the following for a canine of unknown signalment. 13 Sep 2019*: Pet owner applied FRONTLINE PLUS DOG 5-22 LBS (unsubstantiated) (lot unknown, reporter refused). 1 vial was applied to the skin down the back. 27 Sep 2019*: Pet owner seeing fleas on the dog. It is unknown if they presented to a veterinary clinic. It is unknown if any treatments have been administered. Their current condition is unknown. It is unknown what environment the canines frequent. It is unknown if the owner bathes the canines. It is unknown if there are any other pets in the household. The dog has previously received FRONTLINE PLUS at unknown intervals for an unknown length of time. This is the extent of information known as caller refused to report. No further medical information expected.
27-Sep-2019	UAE; 19US057850; -; U.S.A	**Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** F **Sex qualifier:** Unknown **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	21-Aug-2019*	15-Sep-2019*	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 27 Sep 2019, the pet owner reported the following event for female, 75 pound*, 1 year*, Labrador Retriever, all other signalments unknown. 21 Nov 2018*: The pet owner began applying monthly the contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (F61111AR) to the skin between the shoulder blades for the first time year round. 21 Aug 2019*: The owner applied a dose. 15 Sep 2019*: The owner noticed the dog scratching and saw few live fleas on the pet. 21 Sep 2019: The owner applied a dose. 27 Sep 2019: The owner reports still seeing unknown amount live fleas on the dog. There are no other pets in the home. The owner lives in the country and the dog frequently plays outside. The owner is not seeing any flea activity in the home. The dog has not been bathed or swimming. The owner covers and beds where the dog frequents. There is no previous adverse medical history. No further medical information expected.
27-Sep-2019	UAE; 19US057854; FL; 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:** unknown **Was the product used ok?:** Unknown to Company	05-Jan-2019*	15-Jan-2019*	N/A	D-D	Suspected Lack of Efficacy: On 27 Sep 2019, a pet owner reported the following event for 6 cats,with mixed sexes and reproductive statuses, with further unknown signalment. 5 Jan 2019*: The cats received FRONTLINE PLUS CATS (unknown size, lot unknown, package unavailable, product unsubstantiated) in an unknown location and route for the first time this year. The pet owner continues to apply flea prevention monthly around the 5th of each month. There are 5 outdoor dogs who also receive FRONTLINE PLUS monthly (see case 19US057770). 15 Jan 2019*: The pet owner discovered all of the cats had fleas. They were all itchy because of the fleas. 27 Sep 2019: The pet owner has seen fleas all summer long, they have not gone away on any of the animals. 5 of the 6 dogs live outside only and all of the cats live outside. There is urban wildlife present on the acre of property. The property is mostly sand, dirt, and some grass. The house is treated weekly for fleas with an unknown pesticide. The owner was being bitten by fleas prior to the pesticide being used in the house on an unknown date. No further medical information expected.
27-Sep-2019	UAE; 19US057872;	**Species:** Canine **Breed:** Blue	1	1	0	**Product used:** FIPRONIL	01-Sep-2019*	13-Sep-2019	N/A	N/A	Suspected Lack of Efficacy Claim: On 27 Sept 2019, a veterinarian reported the following event for Blue, 6 year old, 55.1 pound,

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	IA; U.S.A	Heeler **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 55.1 lbs				10%/S METHOPRENE 9% SPOT ON **Other products used:** RECOMBITEK LYME - 2126.R0; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					neutered male, Blue Heeler canine. The dog was vaccinated with RECOMBITEK LYME (42222, 21 Sept 2019) 1ml, SC, in the left shoulder on 16 Sept 2014, 6 Oct 2014, 14 Sept 2015, 27 Sept 2016, 26 Sept 2017, and 14 Sept 2018. The dog tested negative for Lyme on 10 Sept 2018 via Idexx 4Dx. 13 Sept 2019: The dog tested positive for Lyme disease via Idexx 4Dx. No treatment has been initiated at this time. No further information available at this time. UPDATE 27 Sep 2019: Per the veterinarian, the pet is asymptomatic. The pet owner claims to administer a tick preventive to the pet, but the veterinarian cannot confirm this. A Quant C6 test is planned. No further information available at this time. UPDATE 23 Oct 2019 per medical record received on 15 Oct 2019: The pet is on FRONTLINE PLUS (product unsubstantiated) from a farm store. 2 Oct 2019: The result of a Quant C6 test was 49 (0-30). The pet was treated with doxycycline. A follow up Quant C6 test is planned in 6 months. No further medical information at this time.
27-Sep-2019	UAE; 19US057881; ME; 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?:** No (Treatment / vaccination program not respected)	27-Sep-2019	27-Sep-2019	0 Day(s)	D-D	Suspected Adverse Event: On 27 Sep 2019 the pet owner called in the following event for a feline of unknown signalment. 27 Sep 2019: The owner applied an unknown amount of FRONTLINE PLUS CATS (lot unknown, owner not queried) topically to an unknown location. The pet was moving and the owner put the product further down the pets back and the pet licked the hair coat. The cat is now licking his lips and blinking his eyes and an increased rate. The pets health prior to application is unknown. No further medical information expected.
27-Sep-2019	UAE; 19US057887; FL; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** 10 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-Sep-2019	14-Sep-2019*	1 Week(s)	D-D	Suspected Adverse Event: On 27 Sept 2019, the pet owner reported the following event for Boosie, a 10.0 pound*, 4 year old*, intact male African Beijing mix. 7 Sep 2019: The pet owner applied 1 dose of FRONTLINE PLUS DOG 5-22LBS (S61902AL) between the shoulder blades, in one spot, for the first time on the dog. 14 Sep 2019*: The dog experienced redness, bumps and scabbing at the application site. The dog did not present to the veterinary clinic and was not treated. It is unknown if the dog has recovered. There is another dog in the home that is not experiencing adverse effects. Another case was previously reported. See Case 19US053666. No further medical information expected.
30-Sep-2019	UAE; 19US057907; IA; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** N **Sex qualifier:**	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON	01-Sep-2019*	02-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sept 2019, the owner reported the following event for Feline (all other signalments unknown). Unknown date: One vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) was applied between the shoulder blades. It is unknown if the pet received the product before. On

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		Unknown **Age:** - **Weight:** Unknown				**Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					another unknown date. The owner noticed ticks attached to the cat. The owner removed the ticks and they were dead. The pets environment is unknown. It is unknown if there are any other animals in the household. No further medical information is expected.
30-Sep-2019	UAE; 19US057910; -; 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	27-Sep-2019	30-Sep-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019 a pet owner reported the following event for a feline of unknown signalment. 27 Sep 2019: The owner applied FRONTLINE PLUS CATS (lot unknown, package unavailable) to the cat, it is unknown if this was the first dose or if fleas were present. 30 Sep 2019: The owner saw a single fleas. The cat is indoor only, no other pets in the house. All other details unknown. No further medical information expected.
30-Sep-2019	UAE; 19US057917; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 8 - 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	18-Jul-2019	30-Sep-2019	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, the owner reported the following event for two 8-12 pound felines (all other signalments unknown). 18 Jul 2019: Started on monthly doses of FRONTLINE PLUS CATS (lot unknown, product unavailable) topically between the shoulder blades by the owner. The cat had fleas for approx. a month before the first application. 18 Jul 2019*: The owner continued to see fleas on the cats. 18 Sep 2019: Another dose of FRONTLINE was applied. The owner continues to see fleas on the cats. The owner never saw any flea activity in the home. The owner had the house treated. The cats are strictly indoor. The owner has bathed the cats with a flea shampoo. No further medical information expected.
30-Sep-2019	UAE; 19US057919; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 92 - 105 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-Aug-2019	30-Sep-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sept 2019, the owner reported the following event for a Boxer canine weighing 92 pounds and a Rottweiler canine weighing 105 pounds (all other signalments unknown). 23 Aug 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (T61504AX) was applied between the shoulder blades. 1 Sept 2019: The owner started to notice fleas on the pet for the first time. 23 Sept 2019: Another vial was applied. 30 Sept 2019: The issue is still ongoing. No fleas have been noted in the household The dogs have access to a fenced in yard. The dogs have received the product year round since 2018* with no issue. No further medical information is expected.
30-Sep-2019	UAE; 19US057920; DE; U.S.A	**Species:** Feline **Breed:** Calico **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s)	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products**	01-Sep-2019*	10-Sep-2019*	9 Day(s)	D-D	Suspected Adverse Event and Lack of Efficacy: On 30 Sep 2019, the pet owner reported the following event for Zeva, a 3 year old*, spayed female, 12 pound, Calico. Sep 1 2019*: The cat received one vial of FRONTLINE PLUS CATS (S40601AX) from an 8 pack. Fleas were seen prior to product application.

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		Weight: 12 lbs				**used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					10 Sep 2019*: The cat began experiencing hair loss at application site. The pet owner is also still noticing fleas on the pet. 20 Sep 2019*: The cat presented to the veterinary clinic. It is unknown if diagnostics were performed. The cat was treated with unknown antibiotic injection, unknown steroid injection, and Revolution. The cat's current condition is ongoing. This is the first time the cat has received FRONTLINE PLUS CATS. The cat has no other drug or vaccine reactions. There are no other pets in the home. No further medical information expected.
30-Sep-2019	UAE; 19US057922; TX; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Sep-2019*	29-Sep-2019*	4 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, a pet owner reported the following event for a canine of unknown signalment. 1 Jul 2019*: The dog began receiving monthly applications of FRONTLINE PLUS DOG 45-88 LBS (Unsubstantiated) (Lot Unknown, Package Unavailable) in an unknown manner. It is unknown if fleas were seen prior to application. 1 Sep 2019*: The most recent application was applied. 29 Sep 2019*: The pet owner noticed a few black bugs on the dog. The owner was not sure if they were fleas. It is unknown if there are any other pets in the home. It is unknown if the dog receives baths or goes to grooming. It is unknown what the outside environment is like or how much exposure the dog has outside. No further information expected.
23-Sep-2019	UAE; 19US057926; PA; U.S.A	**Species:** Canine **Breed:** Siberian Husky **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 85 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Phenobarbital; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	18-Jan-2015*	01-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, the pet owner reported the following event for Patsy, a 4 year old, 85 pound*, spayed female, Siberian Husky. 18 Jul 2019, 18 Aug 2019, and 18 Sep 2019: The patient got their monthly dose of FRONTLINE PLUS DOG 45-88 LBS (S62111AL), the dog has gotten FRONTLINE monthly since Jan 2015*. The owner purchased a 3 pack this past purchase. It was applied between the shoulder blades. 1 Aug 2019*: The owner noticed fleas started to be seen on the animal. 13 Sep 2019*: The owner bathed the animal with Dawn Dish Soap. The pet goes outside. The pet is showing no skin issues, but is itching due to the fleas. There are no fleas in the home, and no fleas on the owner. The patient's current condition is ongoing. There is a total of 2 canines and 1 feline in the household. Patsy was also reported to have a history of seizure and has been on daily Phenobarbital 600 MG BID since an unknown date. The other dog has a lack of efficacy, see case 19US56549. The cat also has a lack of efficacy, see case 19US057932. No further medical information expected.
23-Sep-2019	UAE; 19US057932; PA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 17.00 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**	18-Jan-2003*	01-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 23 Sep 2019, the pet owner reported the following event for Felix, a 17 year old, 7 pound*, neutered male, Domestic Shorthair 18 Jul 2019, 18 Aug 2019, and 18 Sep 2019: The patient got their monthly dose of FRONTLINE PLUS CATS(lot unknown, package unavailable), the cat has gotten FRONTLINE monthly since Jan 2003*. The owner purchased a 3 pack this past purchase. It was applied between the shoulder blades. 1 Aug 2019*: The owner noticed fleas started to be seen on the animal. 13 Sep 2019*: The owner bathed the animal with Dawn Dish Soap. The pet goes outside. The pet is showing no skin issues, but is

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						ok?: Yes					itching due to the fleas. There are no fleas in the home, and no fleas on the owner. The patient's current condition is ongoing. There is a total of 2 canines and 1 feline in the household. The dogs each have a lack of efficacy, see case 19US056549 and 19US057926. No further medical information expected.
30-Sep-2019	UAE; 19US057933; -; U.S.A	**Species:** Canine **Breed:** Dachshund **Sex:** F **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 18 - 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	10-Jun-2019*	10-Sep-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, the pet owner reported the following event for Ellie, a 13 year*, 18-20 pound*, spayed female, Dachshund mix. 10 Jun 2019*: The owner started applying the contents of 1 vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown/ package unavailable) to the skin between the shoulder blades monthly for the first time of the season. 10 Aug 2019*: A dose was applied. 10 Sep 2019: The owner reported seeing 2-3 fleas on pet. The owner applied a dose. 12 Sep 2019: The dog was bathed with Dawn dish soap. The owner reported seeing more fleas in the bathtub. The dog does not have any prior skin issues. The owner does report having fleas last year. There are no other pets in the home. The owner lives in a suburban community and has seen opossums in the backyard. The dog is indoors mostly and goes outside for very short periods of time. The owner reports there are fleas inside the home and biting her brother. No further medical information expected.
30-Sep-2019	UAE; 19US057941; IN; U.S.A	**Species:** Canine **Breed:** Basset Hound **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 50 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn dishsoap; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	13-Apr-2019*	30-Sep-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019 an animal owner reported the following event in Rusty, an 8 year old, 50 pound*, male neutered, Basset Hound. 13 Apr 2019*: Canine started receiving monthly doses of FRONTLINE PLUS DOG 45-88 LB (S62111AL). There were fleas seen at time of administration. 13 Sep 2019: The canine was administered 1 vial of FRONTLINE PLUS between the shoulder blades. There were fleas seen at time of administration. 30 Sep 2019: The canine continues to have fleas. It was reported that the canine is bathed with Dawn dish soap twice weekly. The canine has access to outdoors. There are no other pets in the household. No further information provided.
30-Sep-2019	UAE; 19US057947; NY; U.S.A	**Species:** Canine **Breed:** Greyhound **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 75 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	07-Apr-2019	30-Sep-2019	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019 the pet owner reported the following event for a 75 pound, female Greyhound of unknown further signalment. 7 Apr 2019: Started on FRONTLINE PLUS DOG 45-88 LBS (lot number unknown, package unavailable),1 vial topically, in between the shoulder blades, once monthly. The pet owner claimed she was not seeing any fleas on the pet at the time of application. 30 Jun 2019: The pet owner reported seeing an unknown number of fleas on the canine and inside the home. 9 Aug 2019: The pet owner bathed the canine with Dawn dish soap. 7 Sep 2019: The most recent dose was applied. Currently, the pet owner is still seeing fleas on the pet and inside the home. The canine spends the majority of the time inside the home with access to an outside lawn. there are no other pets in the household. no further medical information is expected.

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30-Sep-2019	UAE; 19US057952; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 23 - 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	09-Sep-2019	21-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, the owner reported the following event for an approx. 23-24 pound canine (all other signalments unknown). 9 Sep 2019: First dose of FRONTLINE PLUS DOG 23-44 LBS (R60107AX) topically between the shoulder blades, by the owner. The dog did not have fleas prior to the application. 21 Sep 2019*: The owner started seeing fleas on the dog. 28 Sep 2019: Another dose of FRONTLINE was applied. The owner is still seeing a moderate amount of fleas on the dog. The owner is not seeing fleas in the home. The dog goes outside for potty breaks in an open yard with a tree and a deck. No further medical information expected.
30-Sep-2019	UAE; 19US057961; NJ; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 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?:** Yes	22-Jun-2019*	30-Sep-2019*	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, the pet owner reported the following event for a 10 year old, male neutered, Jun 2019: The dog was not having an issue with fleas. The owner purchased a 3 pack of FRONTLINE PLUS DOG (product unsubstantiated, S6172AL lot invalid) and applied 1 vial in one area between the shoulder blades for the first time this year. 20 Sep 2019*: There were 1-3 fleas on the dog. The owner bathed the dog in an unknown fleas shampoo. 22 Sep 2019*: 1 vial of FRONTLINE was applied. 30 Sep 2019: 1-3 fleas on the dog. The dog goes out for potty breaks and walks two to three times a day in a neighborhood where other dogs are present. The dog does not have a history of skin issues. There are no fleas seen in the home. No further information.
30-Sep-2019	UAE; 19US057970; MO; U.S.A	**Species:** Feline **Breed:** Ragdoll **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 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	20-Sep-2019	21-Sep-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: 30 Sep 2019: An owner reported the following event in Dominic, a 7 year old, 12 pound, neutered, male, Ragdoll feline. 20 May 2019: The owner administered one FRONTLINE PLUS CATS (S40815AW) topically at the base of the skull for the first time. 5-6 fleas were seen at the time of application. 20 Sep 2019: The owner administered one dose topically at the base of the skull for the fifth time. It is unknown if fleas were seen. 21 Sep 2019: The owner combed out 5-6 fleas. There is one other cat in the home treated with Pet Armor . Both cats are indoor outdoor in a forest environment. The status of the cat is unknown. No further medical information expected.
30-Sep-2019	UAE; 19US057977; MI; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Neutered **Age:** - **Weight:** 12.5 - 14 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	23-Sep-2019	01-Jul-2019*	N/A	D-D	Suspected Adverse Event and Suspected Lack of Efficacy Claim: On 30 Sep 2019, the pet owner reported the following event for a 12.5 pound*, castrated feline of further unknown signalment and a castrated 14 pound* feline of further unknown signalment. Unknown dates: Each feline began receiving one vial of FRONTLINE PLUS CATS (FL+) (P40414) applied topically between the shoulder blades. The frequency of subsequent applications which have all been applied in like fashion could not be confirmed because it varied: some years the reporter would apply one vial monthly on unknown dates year-round, and other times including for 2018 – 2019, she applied the product seasonally during the warmer months. Fleas have never been present on either indoor/outdoor feline at the times of FL+ application. 1 May 2019*: The first FL+ application of 2019 was applied and fleas were not present on either feline at the time of product use.

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											Except for Aug 2019, each feline has since received one vial of FL+ applied monthly on the following dates: 1 Jun 2019*, 1 Jul 2019*, and 23 Sep 2019. Fleas were not present at the time of the June application, but were present on each cat at the July application. It cannot be confirmed how many fleas were seen per feline at the time of their respective FL+ applications. 1 Jul 2019*: Almost immediately following each cat's FL+ application, they became itchy presumably due to the presence of fleas. It cannot be confirmed if either feline's pruritus resolved at any point before their subsequent FL+ application. 23 Sep 2019: Like in July, both felines were very itchy almost immediately following FL+ application. The reporter also describes both cats as acting strange, but she cannot further describe their behaviors other than constantly licking themselves. She also observed one cat laying out in the yard which is atypical behavior. Unknown date: An unknown duration after FL+ application, the pet owner is finding a large volume of fleas on both cats who
29-Sep-2019	UAE; 19US057978; IA; U.S.A	**Species:** Canine **Breed:** Welsh Corgi **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 34 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	29-Sep-2019	29-Sep-2019	0 Day(s)	D-C	Suspected Adverse Reaction: On 29 Sep 2019, the following event was reported to Safety Call International (SCI) by the pet owner for Dallas, a 6 year old, 34 pound, intact female, Welsh Corgi. 29 Sep 2019: The pet owner applied one vial of FRONTLINE PLUS DOG 23-44 LBS (H64806AX) topially between the shoulders. Almost immediately after administration the dog began circling to the left and couldn't walk in a straight line. The owner did wash the area of application with Dawn dish soap. The owner crated the dog and she calmed some, but still wanting to circle to the left. No further medical information expected. The dog previously received Frontline Plus in the past on occasion, without adverse effects. UPDATE 30 Sep 2019: The dog presented to the veterinary clinic. The veterinarian found a large waxy plug in the ear that they suspect is likely the cause of the symptoms. It is unknown if treatment has been provided. The dog's current condition is ongoing. No further medical information expected.
30-Sep-2019	UAE; 19US057980; -; U.S.A	**Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 63 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Hydrogen peroxide solution with Dawn; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	15-Aug-2019*	09-Sep-2019*	25 Day(s)	D-D	Suspected Lack of Efficacy Claim and Adverse Event: On 30 Sep 2019, the pet owner reported the following event for Maddie, a 63 pound, 11 year (4 Jul 2008), spayed female, German Shepherd mix. 15 Jan 2009*: The owner applied the contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S61111AR) to the skin between the shoulder blades year round for the first time. 14 Aug 2019*: The dog was sprayed by a skunk and washed with hydrogen peroxide solution that included small amount of Dawn dish soap. 15 Aug 2019*: A dose was applied. 09 Sep 2019*: The owner noticed the pet scratching and hot spots. The pet was taken to the vet and prescribed unknown steroids, unknown pain medication, and unknown medicated shampoo/ conditioner. 12 Sep 2019*: The owner noticed some relief with the medications, but the pet was still scratching. 29 Sep 2019: The owner bathed pet with unknown flea shampoo and found 20 fleas on the pet. There are no other pets in the home. It is unknown how often the pet was being bathed with medicated shampoo. There is no prior history of skin issues or fleas. The pet is mostly inside but does go for walks outside to an unknown environment. The owner reports

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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
											spraying his house with unknown pest repellent, but has not seen any flea activity within the home. The owner has not seen any fleas today. No further medical information expected.
30-Sep-2019	UAE; 19US057983; OH; U.S.A	**Species:** Canine **Breed:** Canine various breeds **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-Sep-2019*	28-Sep-2019	27 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 28 Sep 2019, the pet owner reported to a social media outlet the following event for an unknown amount of dogs with unknown signalment. This report was discovered on 30 Sep 2019. Unknown date: The dogs began receiving FRONTLINE PLUS DOG (unsubstantiated) (lot and expiration unknown, package unavailable). It is unknown if the product had been received previously. 28 Sep 2019: The owner is still noticing an unknown amount of fleas. The dogs' excursion details are unknown. There were no other details given in the social media post. No further medical information expected.
30-Sep-2019	UAE; 19US058000; OH; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 15.00 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	10-Sep-2019	30-Sep-2019	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019 an animal owner reported the following issue with a 15 year old cat. All other signalment unknown. 10 Aug 2019: The feline was administered 1 vial of FRONTLINE PLUS CATS (lot S41103AW) in between the shoulder blades. Flea dirt seen at time of administration. 10 Sep 2019: The feline was administered 1 vial of FRONTLINE PLUS. 4 or 5 fleas were seen at time of administration. 30 Sep 2019: The animal owner is still seeing fleas. The feline has been receiving monthly doses of FRONTLINE PLUS since 2004*. There is a bunny that lives outdoors. No fleas seen on bunny. The feline is indoor only. No further information provided nor expected.
20-Sep-2019	UAE; 19US058004; NY; U.S.A	**Species:** Feline **Breed:** - **Sex:** - **Sex qualifier:** - **Age:** - **Weight:** -	-	-	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** - **Was the product used ok?:** -	N/A	N/A	N/A	N/A	Product Quality: On 20 Sep 2019 a pet owner reported the following issue with one 3 pack of FRONTLINE PLUS CATS (S40901AW). The owner applied all three doses to her cats. The package was intact and she didn't notice any damage to any of the vials prior to using them. When the owner opened the last package to apply one more vial to the cats she noticed the vial had a lot more FRONTLINE PLUS in it than the previous 3 did. She said the old package (S40901AW) only had about ½ of the amount that this new package did. She threw away the empty vials and the packaging from the 3 pack so product is not expected to be returned. She did not take any photographs of the packages. She does not believe the new package of FRONTLINE PLUS has an issue. No further information.
30-Sep-2019	UAE; 19US058006; WI; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 50 - 82 lbs	3	3	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Jan-2009*	30-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, the pet owner reported the following event for Cooper, a 10 year old*, 62 pound*, neutered male, unknown breed canine; Fritz, a 5 year old*, 82 pound*, neutered male, unknown breed canine; and Wilson a 1 year old*, 50 pound*, neutered male, unknown breed canine. Jan 2009*: The pets started receiving monthly, year round treatments of FRONTLINE PLUS DOG 45-88 LBS. 1 Aug 2019*: The owner applied one vial FRONTLINE PLUS DOG 45-88 LBS(S62408AX) topically between the shoulder blades to each pet.. 30 Aug 2019*: The owner noticed a large amount of fleas on the pets and in the home. 1 Sep 2019*: The owner applied FRONTLINE PLUS to the pets.

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											26 Sep 2019*: The owner continues to see fleas on the pets and in the home. The pets were bathed in Sergeants flea and tick shampoo. 30 Sep 2019: The pet owner continues to see a large amount of fleas on the dogs and in the home. The dogs have access to a grass yard and urban wildlife is seen in the yard. The dog Wilson was adopted in May 2019 and there were no fleas present on him prior to application of FRONTLINE PLUS. The pets receive FRONTLINE PLUS every month year round. There is a cat in the home, see case 19US058013. No further medical information expected.
30-Sep-2019	UAE; 19US058008; OH; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **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	24-Jul-2019	29-Sep-2019	5 Week(s) 1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019 the pet owner reported the following event for a 17 pound canine of unknown further signalment. 24 Jul 2019: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (lot number unknown, package unavailable), 1 vial topically, in between the shoulder blades. The pet owner saw no fleas on the pet at the time of application. 24 Aug 2019: The most recent dose was applied. 29 Sep 2019: The pet owner saw approximately 2 fleas on the canine and none inside the home. The canine spends the majority of the time inside the home with access to an outside lawn and there are no other pets in the household. No further medical information is expected.
30-Sep-2019	UAE; 19US058012; PA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 5 - 22 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	30-Jul-2019*	30-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019 a pet owner reported the following event for two dogs, between 8 and 10 years old and between 5 and 22 pounds, other signalment unknown. May 2019*: Owner applied FRONTLINE PLUS DOG 5-22 LBS (S66515AL) to the skin between the animal's shoulder blades for the first dose of the season. 30 Aug 2019*: Owner saw 2 fleas on one dog, applied FRONTLINE PLUS. 23 Sep 2019*: Owner saw 2 fleas on one dog. Owner has not seen any fleas in the home. The dogs live inside, going outside only to go potty in a fenced in yard, that is half grass and half cement with some bushes and no wildlife seen. Owner hasn't treated the yard or the home. It is unknown if the dogs have received baths. The owner has used the product seasonally for an unknown amount of years. There are 6 other dogs in the home who are hairless and the owner does not use any flea preventative on them because she says hairless dogs do not get fleas. No further medical information expected.
30-Sep-2019	UAE; 19US058019; NC; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** X **Sex qualifier:** Mixed **Age:** 12.00 Year(s) **Weight:** 14 - 16 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	08-Aug-2009	01-Sep-2019*	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, a pet owner reported the following event in 2 dogs: Ollie, a 13 year old, 14 pound, intact male Shih Tzu, and Izzy a 16 pound, 12 year old, spayed female, Terrier mixed breed dog. 8 Aug 2019*: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (R61013AL) to both dogs. The owner has been using FRONTLINE PLUS on the dogs since 2009* monthly, year round. 1 Sep 2019*: The owner discovered both dogs had fleas. The owner also discovered fleas on one cat in the house. 8 Sep 2019*: The owner applied FRONTLINE PLUS DOG in between the shoulder blades to both of the dogs. 9 Sep 2019*: The owner was still seeing fleas on the dogs. 19 Sep 2019*: The dogs were bathed in an unknown flea shampoo.

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											20 Sep 2019*: The owner is still seeing fleas on both dogs. The dogs have access to the back yard which is a ½ acre of grassy area. Ubran wildlife is present in the area and frequent the neighborhood. The yard was treated with an unknown pesticide. There is a cat in the home that is strictly indoor and was not treated with any flea prevention prior to 8 Sep 2019*. The cat is receiving Sentry Fiprogard. No further medical information expected.
30-Sep-2019	UAE; 19US058031; PA; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 9 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	23-Sep-2019*	29-Sep-2019	6 Day(s)	D-D	Suspected Adverse Event: On 30 Sep 2019, the pet owner reported the following event for Sox, a 9 pound*, 4 year old, male neutered, Domestic Shorthair. 23 Sep 2019*: 1 vial of FRONTLINE PLUS CATS (S41003AW) in one area between the shoulder blades for the first time. 29 Sep 2019: The pet owner noticed a sore on the cats back in between his shoulder blades. 30 Sep 2019: He presented to the veterinarian for the sore. A physical exam was done and an unknown topical antibiotic spray was applied. The owner is unsure if he has applied FRONTLINE in the past. There is one other cat in the home that has FRONTLINE applied an is not having any problems .No further medical information is expected.
30-Sep-2019	UAE; 19US058032; FL; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 82 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Adam's Flea and Tick Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Mar-2019*	30-Mar-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019 a pet owner reported the following event for Cate, an 82# male dog of unknown other signalment. Mar 2018*: Owner started using FRONTLINE PLUS DOG 45-88 LBS (R61201BR) to the skin between the animal's shoulder blades monthly. Mar 2019*: Owner started seeing fleas on the dog and started applying FRONTLINE PLUS to the dog every 21 days. Unknown Date: Administered Capstar. 30 Sep 2019: Most recently applied FRONTLINE. Cato is continuing to lick, bite, and scratch due to fleas. The owner is bathing him twice a week for 2 month with Adam's flea and tick shampoo and states 50 fleas came off during the most recent bath. Seeing 1-5 fleas on him otherwise. The dog lives inside, going outside on a leash in a yard where the owner has seen wildlife. No fleas seen in the home. Terminix has treated the yard and the home. Adams flea and tick spray has also been used in the home. There are 3 cats in the home that are indoors only, confined to the sun room, and owner does not see fleas on them. They are on FRONTLINE. There is one other dog in the home who has its own case: 19US058244. No further medical information expected.
30-Sep-2019	UAE; 19US058042; CO; U.S.A	**Species:** Canine **Breed:** Poodle (Standard) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 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	26-Sep-2019	30-Sep-2019	4 Day(s)	D-D	Suspected Adverse Event: On 30 September 2019, the owner reported the following event for Ollie, a 2 year old, 60 pound, neutered male Poodle (Standard). 26 September 2019: The groomer told the owner the dog had lice (lice not specified) and one vial of FRONTLINE PLUS DOG 45-88 LBS (S61810AX) was applied topically for the first time. 30 September 2019: The dog was very anxious, can't get comfortable, and scratching. The owner is not finding anything on the dog's body. The dog has not been seen by the vet and the owner is monitoring his condition. No further information available.

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30-Sep-2019	UAE; 19US058049; IN; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** X **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** Unknown	28	22	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Sep-2019*	29-Sep-2019	1 Day(s)	D-D	Suspected Adverse Event: On 30 Sep 2019, the pet owner reported the following event for approximately 28 cats, 8 months to 6 years old*, of otherwise unknown signalment. Unknown date: The pet owner noticed fleas on the 28 outdoor cats. 28 Sep 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S41307AW), per cat, between the shoulders, in one spot, for the first time this year to 22 cats. The pet owner applied one dose of FRONTLINE PLUS CATS (lot unknown) (package unavailable), per cat, between the shoulders, in one spot, to 6 cats, for the first time this year. 29 Sep 2019: The 22 cats that received lot S41307 AW began experiencing lethargy, vomiting, and diarrhea. The other 6 cats are asymptomatic. None of the cats have presented to a veterinarian or have been treated. Their current condition is ongoing. The pet owner mentioned that these cats are strictly outdoor farm cats and she has used FRONTLINE PLUS CATS in the past, but it is unknown if these specific cats have received FRONTLINE PLUS CATS in the past. The cats have exposure to wildlife and other felines of unknown vaccine status. No further medical information expected.
30-Sep-2019	UAE; 19US058056; -; 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?:** No (Treatment / vaccination program not respected)	02-Jan-2019	25-Sep-2019	23 Day(s)	D-D	Suspected Lack of Efficacy On 30 Sep 2019, animal owner reported the following event for 4 unknown signalment felines. 02 Jan 2019: Started monthly FRONTLINE PLUS CATS (S40815) topically between the shoulder blades. 02 Sep 2019: A dose was applied. 25 Sep 2019: The cats began scratching, itching and the pet owner saw live fleas on the cats. The pet owner applied another dose. 30 Sep 2019: The pet owner is still seeing fleas and the cats have sores on thier body from scratching. The cats were ferral cats and mostly outdoors until a few months ago. The cats are indoors only. The pet owner advised she has cleaned the environment. The cats have not been bathed. There are no other pets in the home and there are stray cats around the house. No further information expected.
30-Sep-2019	UAE; 19US058068; PA; U.S.A	**Species:** Feline **Breed:** Feline various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	15-Jul-2019*	30-Sep-2019	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, the pet owner reported the following event for a 2 cats with unknown signalment. 15 Sep 2019: The cats began receiving FRONTLINE PLUS CATS (unsubstantiated) (lot unknown, package unavailable) from a new 6 pack. The cats receive the product on a monthly basis, all year round. The product application details are unknown. Fleas were seen prior to product application. 30 Sep 2019: The cats presented to the veterinary clinic for routine exam. The veterinarian found an unknown amount of fleas on both cats. It is unknown if treatments have been provided. The clinic veterinarian is recommending to switch to a different prevention. The cats' current condition is ongoing. Both cats are indoor/outdoor. There are 2 cats and no other animals in the home. Caller did not wish to answer any further questions. No further medical information expected.
30-Sep-2019	UAE; 19US058087;	**Species:** Feline **Breed:** Feline	6	6	0	**Product used:** FIPRONIL	07-Sep-2019	08-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim and Adverse Event: On 30 Sep 2019 a pet owner reported the following event for 6 cats, ages 1

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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
	MN; U.S.A	(unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** Unknown				10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					year to 16 years old, other signalment unknown. 7 Sep 2019: Owner applied FRONTLINE PLUS CATS (lot unknown, Package unavailable) in an unknown location, for the first time in an unknown time frame. There are six cats in the home who live inside and outside. The owner reports the cats are still scratching, she is not seeing fleas on the cats, but owner is getting by fleas in the home. It cannot be clarified if the cats were scratching before she applied the FRONTLINE, but the owner notes she has been using the product for years, but just when she knows she needs to by when she sees the cats scratching and their fur moving around. The owner declined to make a report or give further details. She also mentioned a 7th cat that died after the application: see case 19US058092. No further medical information expected.
30-Sep-2019	UAE; 19US058092; MN; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **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	07-Sep-2019	16-Sep-2019*	9 Day(s)	D-A	Suspected Adverse Event: On 30 Sep 2019 a pet owner reported the following event for a 12 year old cat of unknown other signalment. 7 Sep 2019: Owner applied FRONTLINE PLUS CATS (lot unknown, Package unavailable) in an unknown location, for the first time in an unknown time frame. Unknown date: The owner found the cat dead. The owner declines to make a report or give further details. She states she does not think it was related to the product. She mentioned this cat while reporting a suspected lack of efficacy for her other 6 cats in case 19US058087. No further medical information expected.
30-Sep-2019	UAE; 19US058100; CA; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 9 - 15 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Burts Bees pet shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	11-Nov-2018*	26-Aug-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, the pet owner reported the following event for a Canine, 7 years old*, 15 pounds*, spayed female, Pug and a 14 year old*, 9 pound*, neutered male, Pomeranian. Unknown Date: The owner notices fleas on pets. 1 Nov 2018* - 25 Aug 2019*: The owner applied 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S62502AW) topically between the shoulder blades. The owner is unsure if the product was applied every month. 26 Aug 2019*: The pet owner notices an unknown amount of fleas on the pets and bathes them in Burts Bees pet shampoo. 30 Sep 2019: The pet owner continues to notice fleas on the pets. The pets have access to a gravel back yard and are leash walked, there is urban wildlife present. There are no other pets in the home. There are no fleas seen in the home. The medical history is unknown. No further medical information expected.
30-Sep-2019	UAE; 19US058119; IL; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 20 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	28-Jun-2019	29-Sep-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, a pet owner reported the following event for Whitney, a 5 year old, 20 pound, spayed female Shih Tzu. 28 Jun 2019: The dog began receiving monthly applications of FRONTLINE PLUS DOG 5-22 LBS (S61902AL) topically between the shoulder blades in one spot for the first time this year. The owner has been treating the dog seasonally during the summer months since 2014*. 28 Aug 2019: The dog received its 3rd application of FRONTLINE. The pet owner was not noticing fleas. 4 Sep 2019: The dog received a bath in a medicated shampoo. The owner was not noticing fleas.

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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?: Yes					28 Sep 2019: The dog received its 4th application of FRONTLINE. The owner was not noticing fleas. 29 Sep 2019: The owner saw 5 live fleas on the dog. There are no other pets in the home. The dog goes outside and lays in the grass. At one point there were stray cats hanging around the property and there is a wild rabbit that comes in the yard. No further information expected.
30-Sep-2019	UAE; 19US058124; -; U.S.A	**Species:** Canine **Breed:** Maltese **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:** dog shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	20-Sep-2019	30-Sep-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 September 2019, the owner reported the following event for Bailey, a 4 year old, 15 pound, neutered male Maltese/Shih Tzu mix. 20 September 2019: The owner saw fleas on the dog. The dog was bathed with dog shampoo and one vial of FRONTLINE PLUS DOG 5-22 LBS (S60401AX) was applied to the skin between the shoulder blades. 30 September 2019: The dog was taken to the groomer and had a medium quantity of fleas on her. The dog has been on FL since the end of June without issues until the most recent dose was applied. The dog is exposed to grass and dirt daily. There aren't any fleas in the home and there aren't any other pets in the home. The dog is treated on a seasonally basis for the past 4 years. No further information.
29-Sep-2019	UAE; 19US058125; -; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	01-Apr-2019*	01-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 29 Sep 2019, the pet owner e-mailed and reported the following for a feline of unknown signalment. Unknown date: Pet owner applied FRONTLINE (unsubstantiated) (lot unknown, reporter refused). An unknown volume per animal via an unknown route at an unknown location. Unknown date: Pet owner seeing fleas on the feline. It is unknown if they presented to a veterinary clinic. It is unknown if any treatments have been administered. Their current condition is unknown. It is unknown what environment the feline frequents. It is unknown if the owner bathes the feline. It is unknown if there are any other pets in the household. The feline has previously received FRONTLINE at unknown intervals for several years. This is the extent of information known as e-mail did not state.
30-Sep-2019	UAE; 19US058133; -; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** M **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	26-Sep-2019	29-Sep-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, the pet owner reported the following event for a male, 10 pound, canine, all other signalments unknown. 26 Sep 2019: The owner applied the contents of 1 vial FRONTLINE PLUS DOG 5-22 LBS (lot unknown/ package unavailable) to the skin between the shoulder blades for the first time. 27 Sep 2019*: The owner took the pet to known active flea area. 29 Sep 2019: The owner saw a heavy burden of dead fleas on the pet then bathed with Dawn dish soap. The owner has not seen any fleas within the home and inquired if she should apply another dose. Home environment is unknown. Unknown if there are any other pets in the household. No further medical information expected.
30-Sep-2019	UAE; 19US058142; PA; U.S.A	**Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON	08-Jul-2019	30-Sep-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, The pet owner reported the following event for a 10 year old*, 20 pound*, unknown female, Shih Tzu. 8 Jul 2019- 8 Sep 2019: The Pet owner applied 1 vial of FRONTLINE PLUS DOG 5-22 LBS topically between the shoulder

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		Age: 10.00 Year(s) **Weight:** 20 lbs				**Other products used:** Hartz flea and tick shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					blades. 5 Sep 2019: The owner is seeing fleas on the pet. There are no fleas seen in the home. 29 Sep 2019: The owner continues to see fleas on the pet and bathed the pet in a Hartz flea and tick shampoo. 30 Sep 2019: The owner continues to see fleas on the pet. The dog has access to a grass yard, and the owner states there is an unknown amount of stray cats present in the yard. There are no fleas seen in the home. There are no other pets in the home. The medical history of the pet is unknown. No further medical information expected.
30-Sep-2019	UAE; 19US058146; NY; U.S.A	**Species:** Feline **Breed:** Siamese **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 10 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	02-Sep-2019	02-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 30 September 2019, the owner reported the following event for Zazzy, a 5 year old, 10 pound, spayed female Siamese cat and one other cat (signalment unknown). 2 September 2019: The cats had fleas and were scratching. One vial of FRONTLINE PLUS CATS (S40601AX) was applied to the skin between the shoulder blades. 27 September 2019: The cats continued to scratch and have fleas, another application was given. Owner started to notice fleas in the home. 29 September 2019: The cats still had fleas and contained to itch and scratch. The cats are indoor and outdoor (environment unknown) and are treated monthly, and has had fleas issues going on 2 months. Jazzy has had vomiting in the past see case 19US060885. There are no other pets in the home. No further information available.
30-Sep-2019	UAE; 19US058151; OH; U.S.A	**Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 10 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	24-Sep-2019	25-Sep-2019	1 Day(s)	D-D	Suspected Adverse Event: On 30 Sep 2019, the pet owner reported the following event for Jake, a 4 year old, neutered male, 10 pound, Chihuahua and Pug mix. 24 Sep 2019: The dog began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown, package unavailable). 25 Sep 2019: The dog began experiencing bloodshot eyes, tremors, anorexia, and diarrhea. The dog presented to the veterinary clinic. An exam and radiographs were performed. The dog was treated with a prescription diet. The pet owner did give a dose of anti-diarrheal she had at home. The dog's current condition is ongoing. This is the first time the dog has received FRONTLINE PLUS. The dog has no other drug or vaccine reactions. There is one other dog in the home. No further medical information expected.
30-Sep-2019	UAE; 19US058153; -; U.S.A	**Species:** Canine **Breed:** Canine various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Dawn; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	10-Sep-2019*	10-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, an owner reported the following event for a Beagle of further unknown signalment and a 13 year old Labrador Retriever of further unknown signalment. UNKNOWN DATE: The pet owner found approximately 10 fleas on the dogs. 10 Sep 2019*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown, package unavailable) topically between the shoulder blades. 10 Sep 2019* to 30 Sep 2019: The owner continues to see sligthly more than 10 fleas on the dogs daily. The dogs are chewing from the fleas. 26 Sep 2019: The dogs were bathed with Dawn. There is also a cat in the home, reference case 19US058164. The

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											dogs are indoor and go outside to use the bathroom. There is carpet and hardwood in the home. The owner vacuums daily. There are no strays or wildlife in the environment. No further information expected. UPDATED 11 Oct 2019: It is unknown if this was the first dose of FRONTLINE or if it was used previously. No further medical information expected.
30-Sep-2019	UAE; 19US058164; -; 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 12% SPOT ON **Other products used:** Dawn; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	10-Sep-2019*	10-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, an owner reported the following event for a feline of further unknown signalment. UNKNOWN DATE: The pet owner found approximately 10 fleas on the cat. 10 Sep 2019*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) topically between the shoulder blades. 10 Sep 2019* to 30 Sep 2019: The owner continues to see sligthly more than 10 fleas on the cat daily. The cat is chewing from the fleas. 26 Sep 2019: The cat was bathed with Dawn. There are also 2 dogs in the home, reference case 19US058153. The cat is indoor and outdoor. There is carpet and hardwood in the home. The owner vacuums daily. There are no strays or wildlife in the environment. No further information expected. UPDATE 11 Oct 2019: It is unknown if FRONTLINE was used prior. No further medical information expected.
30-Sep-2019	UAE; 19US058208; MO; U.S.A	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **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	25-Jan-2017*	01-Sep-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019 the pet owner reported the following event for Harlie, a 15 pound*, 2 year old*, spayed female, Yorkshire Terrier. 25 Jan 2017 - 25 Sep 2019: the owner applied one vial FRONTLINE PLUS DOG 5-22 LBS (F63009BL) topically between the shoulder blades. 1 Sep 2019*: The pet owner noticed about 10 fleas on the dog. 16 Sep 2019: The pet owner continues to see fleas on the pet and bathed in Dawn dish soap. 30 Sep 2019: The pet owner continues to see fleas on the pet. The dog is leash walked outside and has access to a grass yard with tree shrubs and urban wildlife present. There are no fleas in the home. There are 2 cats in the home, see case 19US58218. no further medical information expected.
30-Sep-2019	UAE; 19US058218; MO; U.S.A	**Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 6 - 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	25-Jan-2017*	01-Sep-2019*	7 Month(s) 1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019 the owner reported the following event for Sophie, a 18 year old*, 12 pound*, spayed female, Maincoon Cat and Gracie, a 1 year old*, 6 pound*, spayed female, domestic shorthair. 25 Jan 2017 - 25 Sep 2019: the owner applied one vial FRONTLINE PLUS CATS (package unavailable) topically between the shoulder blades. 1 Sep 2019*: The pet owner noticed 10 fleas on both cats. 30 Sep 2019: The pet owner continues to see fleas on the pets. The cats are indoor only and have no access outside. There is a dog in the home, see case 19US058208. No fleas are seen in the home. No further medical information expected.
30-Sep-2019	UAE; 19US058235; NJ; U.S.A	**Species:** Canine **Breed:** Canine (unknown)	1	1	0	**Product used:** FIPRONIL 10%/S	08-Sep-2019*	09-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, the pet owner reported the following event for a male canine of further unknown signalment.

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		Sex: M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				METHOPRENE 9% SPOT ON **Other products used:** Pet Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company					07 Jul 2019*, 07 Aug 2019*, and 07 Sep 2019*: The dog was bathed with pet shampoo. 08 Jul 2019*, 08 Aug 2019*, and 08 Sep 2019*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 89-132 LBS (P62803AR) topically between the shoulder blades. 09 Sep 2019* to 30 Sep 2019: The owner continues to see anywhere from 1-2 fleas on the dog daily. Dog is chewing daily from the fleas. There are no other pets in the home. There is an outdoor cat that comes in the environment and some wildlife. Owner has not been bit and is not seeing fleas in the home. There is only hardwood in the home. Dog is indoor and goes outside for the bathroom. No further medical information expected.
30-Sep-2019	UAE; 19US058244; FL; U.S.A	**Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 28 lbs	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Adam's Flea and Tick Shampoo; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	29-Mar-2019*	30-Mar-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019 a pet owner reported the following event for Diamond, a 28# female dog of unknown other signalment. 2016*: Owner started using applying FRONTLINE PLUS DOG 23-44 LBS (S61009AL) to the skin between the animal's shoulder blades monthly. Mar 2019*: Owner started seeing fleas on the dog and started applying FRONTLINE PLUS to the dog every 21 days. Unknown Date: Administered Capstar. 30 Sep 2019: Most recently applied FRONTLINE. The owner continuing to see 20 fleas at a time on Diamond and is bathing her every 2 weeks for 2 month with Adam's flea and tick shampoo and states 50 fleas came off during the most recent bath. Seeing 1-5 fleas on him otherwise. The dog lives inside, going outside on a leash in a yard where the owner has seen wildlife. Diamond will also sometimes bolt out the door and chase squirrels in the neighborhood. No fleas seen in the home. Terminix has treated the yard and the home. Adams flea and tick spray has also been used in the home. There are 3 cats in the home that are indoors only, confined to the sun room, and owner does not see fleas on them. They are on FRONTLINE. There is one other dog in the home who has its own case: 19US058032. No further medical information expected.
19-Aug-2019	UAE; 19US058325; SC; 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:** Topical / Cutaneous **Was the product used ok?:** Yes	09-Feb-2019*	10-Feb-2019*	N/A	D-A	Suspected Lack of Efficacy Claim: On 19 Aug 2019, the pet owner reported the following event for a canine of further unknown signalment. UNKNOWN DATE: The pet owner found an unknown number of fleas on the dog. 09 Feb 2019, 09 Mar 2019, 09 Apr 2019, 09 May 2019, 09 Jun 2019, and 09 Jul 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S61902AL) topically between the shoulder blades. 10 Feb 2019* to 01 Aug 2019*: The owner sees fleas on the dog daily. UNKNOWN DATE: The dog passed away from old age. The owner has not been bit. There is another dog in the home reference case 19US049528. There is also an indoor only cat in the home, that is not having issues and is not being treated with any product. The owner has not seen fleas in the home and there is only hardwood in the home. The dogs are indoor and go outside for the bathroom. No further medical information expected.
27-Sep-2019	UAE; 19US058394;	**Species:** Feline **Breed:** Feline	1	1	0	**Product used:** FIPRONIL	11-Aug-2019*	11-Aug-2019*	0 Day(s)	D-A	Suspected Adverse Event: On 27 Sep 2019, the owner called and reported the following event of a feline of unknown signalment

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	NY; U.S.A	(unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown				10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company					Unknown date: The pet began receiving FRONTLINE PLUS CATS (Lot unknown) (reporter no queried). It is unknown how the owner is applying the product. Unknown date: The pet passed away of unknown cause. It is unknown if the pet was experiencing fleas. There are 8 other felines in the home and 2 canines. The environment is unknown. The other pets are experiencing fleas. See cases 19US057904, 19US058463, and 19US058456. Owner did no provide any more information. No further information expected.
27-Sep-2019	UAE; 19US058456; NY; 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:** unknown **Was the product used ok?:** Unknown to Company	11-Aug-2019	12-Aug-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim and Adverse Event: On 27 Sep 2019, the pet owner reported the following event for 4 felines of unknown signament. 10 Aug 2019*: The owner noticed an unknown amount of fleas on the pets. 11 Aug 2019: The pet began receiving FRONTLINE PLUS CATS (Lot unknown) (reporter no queried). It is unknown how the owner is applying the product. After an unknown amount of time, the pets began experiencing hair loss. The hair loss has not resolved. The owner has been noticing fleas off of the pet inside the home. The environment is unknown. It is unknown how long the pets have received Frontline and how often. The pets have not presented to the veterinarian. There a total of 2 canines and 8 felines in the household. The All pets in the home are being treated with FRONTLINE PLUS. See cases 19US057904, 19US058394 and 19US058463. No further medical information expected.
16-Sep-2019	UAE; 19US058457; FL; U.S.A	**Species:** Feline **Breed:** Feline various breeds **Sex:** U **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 12 - 15 lbs	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)	12-Sep-2019*	13-Sep-2019	0 Day(s)	D-D	Suspected Adverse Event: On 16 Sep 2019, the owner reported the following event for 2 felines, 4 year olds, weighing 12-15 pounds, Mixed Breed cats. 12 Sep 2019*: One vial of FRONTLINE PLUS CATS (R41105AW) (outside packaging) with FRONTLINE PLUS DOGS 45-88 (lot unknown)(printed on foil) inside (TPC reported in 19US055094 was applied topically in between the pet's shoulder blades by the owner. Purchased at the end of August. 13 Sep 2019: The owner woke up to large amounts of vomit around the home the owner does not think the vomit came from one cat. The owner has not presented the pets to the clinic. 16 Sep 2019*: The cats have recovered. This is the first application of the product. No further medical information expected.
27-Sep-2019	UAE; 19US058463; NY; 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:** unknown **Was the product used ok?:** Unknown	11-Aug-2019	11-Aug-2019*	0 Day(s)	D-C	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 27 Sep 2019, the pet owner reported the following event for 4 felines of unknown signament. 10 Aug 2019*: The owner noticed an unknown amount of fleas on the pets. 11 Aug 2019: The pets began receiving FRONTLINE PLUS CATS (Lot unknown) (reporter not queried). It is unknown how the owner is applying the product. After an unknown amount of time, the pets began experiencing panting. The owner continues to see fleas. Unknown Date: The panting resolved after an unknown amount of time. The owner has been noticing fleas off of the pet inside the home .

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Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					The environment is unknown. It is unknown how long the pets have received Frontline and how often. The pets have not presented to the veterinarian. There a total of 2 canines and 8 felines in the household. The All pets in the home are being treated with FRONTLINE PLUS. See cases 19US057904, 19US058394 and 19US058456. No further medical information expected.
30-Sep-2019	UAE; 19US058578; NY; U.S.A	**Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 73 lbs*	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** AFOXOLANER 136 MG CHEWABLE TABLETS; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose)	04-Sep-2019*	22-Sep-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 30 Sep 2019, the pet owner reported the following event for a 4 year old*, 73 pound*, neutered male, canine of further unknown signalment. Unknown dates: The canine began receiving one chew of NEXGARD (136 mg) (lot and expiration unknown; package unavailable), PO. A chew has since been given monthly on unknown dates and the last chew was believed to have been given on 4 Aug 2019*. Fleas have never present at the times of NEXGARD administration. 4 Sep 2019*: Because the reporter ran out of NEXGARD, one vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown; package unavailable) was applied topically between the shoulder blades for the first time. No fleas were present on the dog at the time of product administration. 22 Sep 2019: The reporter found a single flea on the dog. Presently, the reporter continues to find a very small volume of fleas on the dog. There is another resident dog in the home that has received NEXGARD (68 mg) and is experiencing a similar issue. Likewise, there is an 18 pound foster dog that was introduced into the home around 9 Sep 2019*. The foster has also received one chew of NEXGARD (28.3 mg) and is experiencing the same issue as both resident dogs. On an unknown date while cuddling one of the dogs, the reporter's husband found a single flea jump onto him and the reporter has only found a single flea bite on her person; however, she is not otherwise finding fleas in the home. There have been no visiting animals and all three dogs go outside for bathroom breaks in a wooded yard which is not fenced in and has lots of local wildlife moving through. Two cases were reported for the other two dogs. Please see cases 19US058027 and 19US058584 for details. No further medical information expected.
26-Sep-2019	UAE; 19US059163; TN; U.S.A	**Species:** Canine **Breed:** Retriever (Golden) **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-Sep-2018*	22-Sep-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 26 Sep 2019, the pet owner reported the following event for a retriever of unknown signalment. Sep 2018*: The pet began receiving monthly FRONTLINE PLUS DOG 45-88 LBS (lot unknown) (package unavailable), applied 1 vial topically between the shoulder blades for the first time. 18 Sep 2019: The most recent dose was applied, FRONTLINE PLUS 45-88 LBS (S63106AX) 22 Sep 2019*: The owner noticed a small amount of fleas on the pet. UNKNOWN: The pet presented to the veterinarian for itching. Treatment initialed with a cortisone injection. It is unknown if the pet recovered. The owner has not been noticing fleas off of the pet inside the home. The yard is fenced. There a total of 3 canines in the household see case 19US057613. No further medical information expected.
25-Sep-2019	UAE; 19US059176; TN; U.S.A	**Species:** Feline **Breed:** Domestic Shorthair	1	1	0	**Product used:** FIPRONIL 10%/S	04-Sep-2019	04-Sep-2019	0 Day(s)	D-D	Suspected Adverse Event: Suspected Adverse Event: 25 Sep 2019: An owner reported the following event in Ozzy, a 9 year old, 8 pound, spayed female Domestic Shorthair.

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*indicates Approximate date or weight

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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
		(Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 8 lbs				METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended)					04 Sep 2019: The owner administered one vial of FRONTLINE PLUS DOGS 45-88 LBS (lot unknown, package unavaliable) that was contained within a 3 pack of FRONTLINE PLUS CATS (R41105AW) topically, at the base of the skull. See case 19US057164 for the product quality report. Immediately post administration the cat started scratching at the application site. 05 Sep 2019: The cat fully recovered without treatment. No further medical information expected.
30-Sep-2019	UAE; 19US060885; NY; U.S.A	**Species:** Feline **Breed:** Siamese **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 10 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?:** No (Treatment / vaccination program not respected)	27-Sep-2019	29-Sep-2019	2 Day(s)	D-D	Suspected Adverse Event On 30 September 2019, the owner reported the following event for Zazzy, a 5 year old, 10 pound, spayed female Siamese cat. 2 September 2019: The cats had fleas and were scratching. One vial of FRONTLINE PLUS CATS (S40601AX) was applied to the skin between the shoulder blades. 27 September 2019: The cats continued to scratch and have fleas (see case 19US058146 for LOE), another application was given. 29 September 2019: Zazzy vomited twice and recovered. Zazzy has had vomiting in the past and is treated with FRONTLINE monthly year round. There is one other cat in the home who doesn't have symptoms. No further information available.
05-Jul-2019	UAE; 19ZA000131; KZN; South Africa	**Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 2.2 kg	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company	03-Jul-2019	04-Jul-2019	1 Day(s)	D-D	As reported by the owner, a dog, male yorkshire, 2 years old, 2.2 kg, in an unknown health condition, received FRONTLINE SPRAY (BN RO3601A, exp date SEP 2019), by spray, dose unknown, on 03 JUL 2019 by owner. The next day the dog had more or less 10 fleas on him and she believes that the Frontline that she had bought in March did not work. The dog receives FRONTLINE SPRAY and is bathed every 2 weeks and the fleas are usually controlled on the day of the spray. The evolution of the event is unknown. This is the extent of information available.
26-Aug-2019	UAE; 19ZA000157; WCP; South Africa	**Species:** Canine **Breed:** Canine (unknown) **Sex:** X **Sex qualifier:** Neutered **Age:** 6.00 Month(s) **Weight:** 8 - 24 kg	3	3	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	22-Aug-2019	24-Aug-2019	2 Day(s)	D-D	SUSPECTED LACK OF EFFICACY: as reported by the owner 3 DOGs (1 female adult , breed daschund, weight 8 kg; 1 male adult breed Border Collie, weight 24 kg; and 1 female breed Border Collie, weight 13 kg - puppy taken as 6 months, unknown health conditions) were treated by the animal owner with 3 bottles of FRONTLINE SPRAY (batch unknown, route of application unknown, dose unknown, storage conditions unknown) recently on 22 August 2019. She complaints she observed on 24 AUG 2019 that the animals still have live fleas on them. She used Frontline spray monthly and wets the animals thoroughly with the Frontline Spray. She also used Fleago in the house and garden. The dogs only go into a paved yard. This is the extent of information available. The case is related to case 19ZA000158 (3 cats treated).

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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
26-Aug-2019	UAE; 19ZA000158; WCP; South Africa	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** X **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 3 - 6 kg	3	3	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company	22-Aug-2019	24-Aug-2019	2 Day(s)	D-D	SUSPECTED LACK OF EFFICACY: as reported by the animal owner, 3 CATS (age taken by default as 2 years, 2 males weight 6 kg and 3 kg and 1 female (3 kg weight), health conditions unknown, breed shorthair) were treated by the animal owner with 3 bottles of FRONTLINE SPRAY (batch unknown, route of application, dose unknown, expire date unknow, storage conditions unknown) recently on 22 August 2019. She complaints she observed on 24 AUG 2019 that the animals still have live fleas on them. She used Frontline spray monthly and wets the animals thoroughly with the Frontline Spray. She also used Fleago in the house and garden. The cats stay inside.The evolution if the event is unknown This is the extent of information available. This case is related to case 19ZA000157.
26-Aug-2019	UAE; 19ZA000159; WCP; South Africa	**Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 5 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	25-Jul-2019	26-Jul-2019	1 Day(s)	D-D	SUSPECTED LACK OF EFFICACY: as reported by the animal owner, two CATS (3 years old, weight 5 kg, sex male, breed domestic, neutered, health conditions prior treatment is unknown) were treated by the animal owner with FRONTLINE PLUS (batch unknown, route and dose of administration unknown, expire date unknown) for cats 10 times now. She reported that the last treatment date was 25 JUL 2019 and the next day 26 JUL 2019 the cats still had live fleas. This has been the pattern with previous treatments as well. No other pets on the premises. No other treatment except deworming done. This is the extent of information available.
16-Sep-2019	UAE; 19ZA000169; KZN; South Africa	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 3.6 kg	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	01-Aug-2019	26-Aug-2019	25 Day(s)	D-D	LACK OF EXPECTED EFFICACY: as reported by the animal owner, a male CAT (breed domestic short hair white tabby, age 1 yrs, +/-3.6 kg, neutered, good health conditions) was treated by the animal owner on 01 AUG 2019 (first time) with the product FRONTLINE PLUS FOR CATS (no batch details, expire date unknown, topically, on the neck, storage conditions normal). Three weeks later, on 26 AUG 2019,the owner noticed live fleas on cat and owner is concerned about LOE. She treated again on 01 SEP 2019 and 01 OCT 2019 and will evaluate end October. There are 2 dogs and a cat on the premises, dogs treated with Capstar. No veterinarian was involved. This is the extent of information available.
17-Sep-2019	UAE; 19ZA000170; WCP; South Africa	**Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** X **Sex qualifier:** Neutered **Age:** 15.00 Year(s) **Weight:** 6 - 7.5 kg	2	2	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes	28-Aug-2019	04-Sep-2019	1 Week(s)	D-D	SUSPECTED ADVERSE REACTION: as reported by the animal owner, 2 domestic stray CATS (1 female, age 15yrs, weighing 6 kg and 1 male, 16 yrs weighing 7.5 kg, both neutered) with good health conditions received on 28 AUG 2019 from the animal owner topically on the neck FRONTLINE PLUS CATS (no batch details, expiry date unknown, 0.5 ml dose). One week later, on 4 SEP 2019 the owner noticed that the male cat had raw sore at application site.The other cat was scratching a lot and also lost some fur, no sore. She has 1 other cat that she did not treat now as it recently had a stroke. Owner is a rescuer and has had many cats over the years, always used FRONTLINE PLUS CATS. No veterinarian was involved. This is the extent of information available.
25-Sep-2019	UAE; 19ZA000174; WCP; South Africa	**Species:** Feline **Breed:** Domestic Shorthair	2	1	0	**Product used:** FIPRONIL 10%/S	24-Sep-2019	24-Sep-2019	0 Day(s)	D-D	SUSPECTED ADVERSE REACTION: As reported by the animal owner on 25 SEP 2019, a spayed female, domestic short hair, tabby cat, age 19 yrs, weight 3 kg in a good health conditions,

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		(Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 19.00 Year(s) **Weight:** 3 Kilograms				METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes					received FRONTLINE PLUS CAT, for the first time (no batch details, expiry date unknown, storage conditions normal) topical on neck (0,5 ml dose, administered by owner) on 23 SEP 2019. Next morning on 24 SEP 2019 (8 hours later) the cat seemed very drowsy. Cat recovered by next day (25 SEP 2019, date choosen by default). Owner also reported cat is normally not really very active. No veterinarian was involved.One other cat was also treated, no adverse effects. This is the extend of information available.

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Worldwide Adverse Event Reports Involving - Human Cases
Reporting Period: 01-Jul-2019 to 30-Sep-2019

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
10-Jul-2019	UHAE; 19BR003309; SP; Brazil	**Sex:** F **Sex qualifier:** Unknown**Age:** 52.00 Year(s) **Weight:** 70 Kilograms	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** buccal **Was the product used ok?:** No (Human exposure (Off label use))	10-Jul-2019	10-Jul-2019	0 Day(s)	H-D	Human Exposure: As reported by the consumer, a woman (female, 52 years old, 70 kg, 1.62 cm) accidentally put the hands on the content of one pipette of FRONTLINE PLUS DOGS S (lot and exp date are unknown) and shortly after put the hands on the mouth. According to the reporter, she felt a bitter taste after having contact with the product, however, she washed her mouth and did not experience any other symptoms. The orientation given to the consumer by the anti-poison centre was to drink water and eat jelly (demulcent). Her current status is unknown. The event occurred on 10 Jul 2019. No further information is available. UPDATE 12 Jul 2019 – The patient was contacted and reported that, in addition to feeling the bitter taste of the product, she also experienced nausea and tingling sensation on the mouth however, the signs improved the day after the event occurred. No further information is expected.
23-Jul-2019	UHAE; 19BR003459; BA; Brazil	**Sex:** M **Sex qualifier:** -**Age:** 10.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical and Opthalmic **Was the product used ok?:** No (Human exposure (Off label use))	23-Jul-2019	23-Jul-2019	Some time	H-D	Human Exposure: As reported by the mother of the human patient (male, 10 years old), on 23 Jul 2019 he accidently sprayed FRONTLINE SPRAY (FL) (lot and exp date unknown) on his hands and then touched his left eye. Some time after product exposure the patient experienced swelling and reddening of the left eye. The doctor diagnosed chemically induced conjunctivitis and oriented washing the eye with saline solution, compress with gaze and saline solution and then drip two drops of cool saline solution or boric acid solution every 2 hours. Signals are still ongoing. No further information is available. UPDATE 25 JUL 2019 - The patient has recovered on date not specified (25 Jul 2019*). No further information is expected. UPDATE 26 JUL 2019 - The date of recovery was confirmed (24 Jul 2019). Also, the patient's mother informed that she followed the doctor's treatment orientations. No further information is expected.
09-Sep-2019	UHAE; 19BR004015; RJ; Brazil	**Sex:** U **Sex qualifier:** -**Age:** - **Weight:** -	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Intentional)	06-Sep-2019*	06-Sep-2019*	0 Day(s)	H-D	Human Exposure: As reported by the human patient, her hands became slightly sticky shortly after intentionally spraying FRONTLINE SPRAY 250 mL (FL) (004/18A, Sep 2020) on them. The product was sprayed on approx. 6 Sep 2019 and it is unknown if the event is ongoing. No other AE was reported. A SLOE case involving the reporter's dog was reported on 19BR004014 and a quality deviation case was also reported on GoTrack (see PRID 493476). Another human exposure to the same product related to the same patient occurred in the past (see 19BR004018). Pictures of the bottle were received. No further information is available.
09-Sep-2019	UHAE; 19BR004018; RJ; Brazil	**Sex:** U **Sex qualifier:** -**Age:** - **Weight:** -	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	2017*	2017*	0 Day(s)	H-D	Human Exposure: As reported by the human patient, her hands became rough after having contact with FRONTLINE SPRAY 100 mL (FL) (lot and exp date are unknown). The date of the event was not informed (2017*). Another human exposure to the same product related to the same patient was reported on 19BR004015. Related cases reported on 19BR004014 and PRID 493476. No further 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
						product used ok?: No (Human exposure (Off label use))					
23-Jul-2019	UHAE; 19FR000904; -; France	**Sex:** F **Sex qualifier:** Unknown**Age:** 11.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** intraocular **Was the product used ok?:** No (Human exposure (Off label use))	05-May-2019	05-May-2019	0 Day(s)	H-D	FR-ANMV-19 CPVL 00977: T0: a child received accidentally a few drops of FRONTLINE SPRAY POMPE in right eye. Within a few sec, she displayed eye pain. Duration of reaction: < or = 30 minutes. Duration of reaction (precision): Ongoing (<10 min). Outcome of SAR: Unknown.
30-Aug-2019	UHAE; 19FR001052; -; France	**Sex:** F **Sex qualifier:** Unknown**Age:** 12.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure (Off label use))	26-Jun-2019	26-Jun-2019	0 Day(s)	H-D	FR-ANMV-19 CPVL 01193: D0: a girl had been applied with FRONTLINE SPRAY POMPE on her hairs, for lice infestation. After one hour, hairs rinsed. During daytime (exact time to onset not specified, estimated less than a few hours), she displayed nausea. D1: at time of phone call to PCC, signs had resolved. Duration of reaction: < or = 24 hours. Duration of reaction (precision): < 24 hours. Treatment of SAR: rinsing. Outcome of SAR: Favorable.
04-Sep-2019	UHAE; 19FR001074; -; France	**Sex:** M **Sex qualifier:** Unknown**Age:** 3.00 Year(s) **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure (Off label use))	22-Jul-2019	22-Jul-2019	Immediately	H-D	FR-ANMV-19 CPVL 01236: D0: that child was accidentally exposed to FRONTLINE SPRAY POMPE (one squirt on face with a few in the eye). Immediately, he displayed eye pain. D1 : completely recovered, no oedema or red eye. Duration of reaction: < or = 24 hours. Duration of reaction (precision): < 20 hours. Treatment of SAR: decontamination as instructed (NOS). Investigations: none. Outcome of SAR: Favorable.
05-Sep-2019	UHAE; 19FR001081; -; France	**Sex:** M **Sex qualifier:** Unknown**Age:** 37.00 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**	23-Jul-2019	23-Jul-2019	0 Day(s)	H-D	FR-ANMV-19 CPVL 01239: T0: a man was accidentally exposed to FRONTLINE COMBO SPOT-ON CHIEN L. The dog bit the pipette and some of the product squirted on his lips. Within 5-6 hours: he displayed lips tingling. Unknown evolution. Duration of reaction: < or = 6 hours. Duration of reaction (precision): ongoing (< 6 hours). Treatment of SAR: rinsing. Outcome of SAR: Unknown.

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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))					
26-Aug-2019	UHAE; 19IT000106; -; Italy	**Sex:** F **Sex qualifier:** -**Age:** - **Weight:** -	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 (zzOff label use / Indication)	04-Aug-2019	04-Aug-2019	N/A	H-D	As reported by the owner 8 hours after the administration of Frontline Combo Spot On Cats to her cat, the owner experienced itching and redness on her face. Owner health is good and she is prone to have skin allergies with similar reactions The face symptoms disappeard quickly after the topical application of a face cream (Bariederm Cream).
23-Aug-2019	UHAE; 19UK002777; -; United Kingdom	**Sex:** U **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	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))	N/A	N/A	N/A	H-E	As reported by the animal owner, SH, a human (signalment otherwise unknown) was accidentally exposed to FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) topically as it bubbled when they snapped it and some leaked onto their skin when they applied it, on approximately 23 AUG 2019. No clinical signs are reported.
01-Jul-2019	UHAE; 19US038119; TN; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 76.00 Year(s) **Weight:** 138 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))	01-Jul-2019	N/A	N/A	H-E	Human Exposure: On 1 July 2019, the following inquiry was reported to Safety Call International (SCI) by a 76 year old, 138 pound, female pet that was exposed to FRONTLINE PLUS CATS (S40410AW) 1 July 2019: The pet owner applied FRONTLINE PLUS CATS to her cat in the moring hours of 1 July 2019. The pet forgot that she applied this product and petted her cart in the area where she applied the product. Exposure to the product was approximately 20 minutes prior to contacting SCI. She immediately washed her hands under water several times, but did not wash them for longer than 10 minutes. The pet owner remains asymptomatic at this time. No other medical information is available.
01-Jul-2019	UHAE; 19US038293; CA; U.S.A	**Sex:** M **Sex qualifier:** -**Age:** 60.00 Year(s) **Weight:** 175 Pounds	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other	01-Jul-2019	01-Jul-2019	0 Day(s)	H-E	Human Exposure: 1-Jul-2019 Safety Call International (SCI) reported the following event. 1-Jul-2019 Animal owner applied FRONTLINE PLUS FOR DOGS(S60402AX) 23-44 lbs. He applied the product to his dog and 15 minutes prior to the call, the dog shook and product accidentally splashed into his eyes. He rinsed briefly and has applied Saline eye drops. He is without symptoms. He does not

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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
						products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure (Off label use))					wear contact lenses but has cataract lenses in both eyes and is concerned.
01-Jul-2019	UHAE; 19US038581; -; U.S.A	**Sex:** M **Sex qualifier:** -**Age:** 70.00 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))	01-Jul-2019	01-Jul-2019	N/A	H-E	Human Exposure: On 1 Jul 2019, the following human exposure was reported to Safety Call International (SCI) by the patient for himself, a 70 year old male of further unknown signalment. 1 Jul 2019: The patient got an unknown amount of FRONTLINE PLUS CATS (S40701AW) on his hand while applying it to his cat approximately 30 minutes prior to contacting SCI. The patient had a small cut on his hand. He quickly washed with soap and water for approximately 1 minute and remained asymptomatic. No further medical information expected.
03-Jul-2019	UHAE; 19US039115; NJ; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	-	-	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))	03-Jul-2019	N/A	N/A	H-E	Human Exposure: On 3 July 2019, the following inquiry was reported to Safety Call International (SCI) by a female pet owner of unknown weight and age, who had an exposure with FRONTLINE PLUS CATS (unknown). 3 July 2019: The pet owner stated that 5 minutes prior to calling SCI, the pet owner got some FRONTLINE PLUS CATS on her finger. The pet owner washed her hands and remains asymptomatic at this time. The reporter refused all other information. No other information is available.
03-Jul-2019	UHAE; 19US039270; -; 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))	03-Jul-2019	03-Jul-2019	N/A	H-E	Human Exposure: On 3 Jul 2019, the pet owner reported the following human exposure for herself, a female of unknown signalment. 3 Jul 2019: The owner was applying FRONTLINE PLUS DOG 45-88 LBS (Lot Unknown) to her dog when some of the product got on her hands. She is asymptomatic. No further medical information expected.
10-Jul-2019	UHAE; 19US040063;	**Sex:** M **Sex qualifier:**	1	0	0	**Product used:** FIPRONIL	10-Jul-2019	10-Jul-2019	N/A	H-E	Human Exposure: On 10 Jul 2019, the following event was reported by the pet owner to Safety Call International (SCI) 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
	PA; U.S.A	Unknown**Age:** 57.00 Year(s) **Weight:** 145.000 Pounds				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))					himself, a 145 lb, 57 year old male. 10 Jul 2019: The pet owner got FRONTLINE PLUS DOG 45-88 LBS (S62111AL) on his hands. He washed with soap and water and is now rinsing his hands, and is asymptomatic. No further medical information expected.
10-Jul-2019	UHAE; 19US040258; OR; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** 82.00 Year(s) **Weight:** 155 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))	10-Jul-2019	10-Jul-2019	0 Day(s)	H-D	Product Quality: On 10 Jul 2019, the pet owner reported the following product quality issue with the packaging of 8 pack of FRONTLINE PLUS CATS (S40601AX). The pet owner cut along the cut line for the 8 pack and inadvertently cut into product, causing it to get all over pet owner. Photograph and product return are not expected, since pet owner does not have access to email and photograph capabilities. No further information expected. Human Exposure: On 10 Jul 2019, the following Human Exposure was reported to Safety Call International (SCI) by the patient, an 82 year old, 155 pound, non-pregnant and non-lactating female. 10 Jul 2019: While cutting along the cut line on a package of FRONTLINE PLUS CATS (S40601AX), the patient ended up cutting into one of the pipettes. She got product all over her left hand. Almost immediately, she developed and itching sensation in her hands. The patient washed her hands with soap and water. The current status of the patient is unknown. It was noted that the patient tends to experience itching when she is nervous, is hard of hearing, and is allergic to seafood, iodine, and amoxicillin. No further information at this time. UPDATE 23 July 2019: Two callback attempts were made by SCI and messages were left requesting follow up. The patient called SCI back to report that she had no other symptoms develop other than the itching but she says she experiences itching anyhow. No other medical information is expected.
11-Jul-2019	UHAE; 19US040584; NJ; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** 62.00 Year(s) **Weight:** 150 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))	11-Jul-2019	11-Jul-2019	N/A	H-E	Human Exposure: On 11 Jul 2019, the following human exposure event was reported by a pet owner to Safety Call International (SCI) for himself, a 150 lb, 62 year old male. 11 Jul 2019: When using FRONTLINE PLUS CATS (S41108AW), the owner got some of the product on his hands while following the directions for opening. He is asymptomatic. The owner mentioned this has happened before on unknown dates. No further medical information expected.
11-Jul-2019	UHAE; 19US040719;	**Sex:** F **Sex qualifier:**	1	0	0	**Product used:** FIPRONIL	11-Jul-2019*	11-Jul-2019	N/A	H-E	Human Exposure: On 11 Jul 2019, the following human exposure was reported to Safety Call International (SCI) by the pet owner 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
	GA; U.S.A	Unknown**Age:** 34.00 Year(s) **Weight:** 187.000 Pounds				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))					themselves, a 34 year old, 187 pound, female human of further unknown signalment. 11 Jul 2019: The pet owner attempted to apply the FRONTLINE PLUS CATS (S41004AW) to her cat, and accidentally exposed herself to unknown amount of product on her lips. The pet owner is asymptomatic. No futher medical information is expected.
18-Jul-2019	UHAE; 19US042165; MD; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 71.00 Year(s) **Weight:** 150 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))	18-Jul-2019	18-Jul-2019	0 Day(s)	H-D	Human Exposure: On 18 Jul 2019, the following event was reported by a pet owner to Safety Call International (SCI) for herself, a 71 year old, 150 lb, female. 18 Jul 2019: Caller states she opened the FRONTLINE PLUS DOG 5-22 LBS (P60507AL) using a scissors a few minutes prior to the call. She then peeled back the foil. She had cut through the vial as well. When she picked up the vial she got product on her fingers. That is when she noticed she had cut herself with the scissors. She is concerned about the exposure especially to her cut. She also has a funny taste in her mouth but the taste resolved during the call as she was drinking coffee. She washed the cut about 15 times, applied antibiotic ointment and a bandage. No further medical information expected. UPDATE 26 Jul 2019: SCI left several messages with the reporter with no update. No further medical information expected.
17-Jul-2019	UHAE; 19US042216; CA; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** 64.00 Year(s) **Weight:** 181.8 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))	17-Jul-2019	N/A	N/A	H-E	Human Exposure: On 17 July 2019, the following inquiry was reported to Safety Call International (SCI) by a 181.8 pound, 64 year old, male pet owner had an exposure with FRONTLINE PLUS DOG 5-22 LBS (S60808AL). 17 July 2019: The pet owner stated that 10 minutes prior to calling SCI, he applied the FRONTLINE PLUS DOG 5-22 LBS to his dog and the product came into contact with his finger. The pet owner washed his hands for 10 minutes with soap and water and remains asymptomatic at this time. No other information is available. UPDATE 18 July 2019: SCI attempted a call back to the caller and left a message requesting follow up. UPDATE 22 July 2019: SCI attempted a call back to the caller and left a message requesting follow up. UPDATE 24 July 2019: SCI received an update that the caller remained asymptomatic. No other information is expected.
23-Jul-2019	UHAE; 19US043200; -; 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**	23-Jul-2019	23-Jul-2019	0 Day(s)	H-D	Human Exposure: On 23 Jul 2019, the following human exposure was reported by the pet owner for herself, a female of further unknown signalment. 23 Jul 2019: The pet owner got an unknown amount of FRONTLINE PLUS (lot number unknown, package unavailable) (product unsubstantiated) on her hands. Afterwards, the pet owners hands smelled. She washed her hands with soap and water. The current status of the pet owner is unknown. Further details regarding the report are not expected as the owner refused to be transferred to Safety Call International (SCI). 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?: No (Human exposure (Off label use))					
23-Jul-2019	UHAE; 19US043393; -; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 79.00 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))	23-Jul-2019	N/A	N/A	H-E	Human Exposure:On 23 July 2019, the following inquiry was reported to Safety Call International (SCI) by a 79 year old, 160 pound, female pet owner that was exposed to FRONTLINE PLUS CATS (S41201AX) 23 July 2019: The pet owner applied FRONTLINE PLUS CATS to her cat 20 minutes prior to calling SCI. She reports that she was applying the product to her cat's back when the cat moved, causing the product to spill onto her palm and fingers. She has washed her hands well with soap and water. She is asymptomatic. The pet owner is allergic to Lidocaine and Codeine, had pacemaker placement in June 2019, and has a history of rheumatoid Arthritis and osteoarthritis. No other medical information is available.
23-Jul-2019	UHAE; 19US043463; OR; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 39.00 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))	23-Jul-2019	N/A	N/A	H-E	Human Exposure: On 23 Jul 2019, the following event was reported by a pet owner to Safety Call International (SCI) for herself, a 39 year old female, other signalment unknown. 23 Jul 2019: Owner stated that she snapped the top of the FRONTLINE PLUS CATS (R41212AW) container, and the product dripped onto her hand. She continued to apply the product to her cat's back, and then washed her hands. She is asymptomatic. No further medical information expected.
24-Jul-2019	UHAE; 19US043637; IL; U.S.A	**Sex:** M **Sex qualifier:** -**Age:** 77.00 Year(s) **Weight:** 195.000 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))	24-Jul-2019	24-Jul-2019	0 Day(s)	H-D	Product quality: on 24 Jul 2019 the pet owner reported the following issue with an 8 pack of FRONTLINE PLUS DOG 23-44 LBS (F61602AX). The owner was opening the package by cutting along the dotted line on the back of the package, when the owner cut into the bottom of 1 vial and the product squirt into the owner's eye. The owner noticed the dotted line ran across the back of the packaging and over 2 of the bottom of the vials. There was no damage to the blister packaging or the outer packaging. No product return or picture is expected as the owner disposed of the defective vial. No further information expected. Human Exposure: On 24 Jul 2019, the following human exposure was reported to Safety Call International (SCI) by the pet owner for himself, a 77 year old, 195 pound, male. 24 Jul 2019: As the owner was cutting a vial of FRONTLINE PLUS DOG 23-44 LBS (F61602AX) per the directions, an unknown amount of product squirted into his right eye approximately 10 minutes prior to contacting SCI. The pet owner wiped his eye with a wet paper towel immediately since his eye was stinging. At the time of the report, the stinging had resolved, and he was to wash his eye with water. It was noted that the patient has type two diabetes and hypertension. 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
											UPDATE: 1-Aug-2019 Per SCI patient rinsed his eye as advised, and symptoms resolved within 2 hours.
23-Jul-2019	UHAE; 19US044129; AL; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 57.00 Year(s) **Weight:** 127.000 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))	23-Jul-2019*	N/A	N/A	H-E	Human Exposure: On 23 Jul 2019, the following human exposure inquiry was reported to Safety Call International (SCI) by the pet owner for themselves, a 57 year old, 127 pound, female human of further unknown signalment. 23 Jul 2019: The pet owner attempted to open the FRONTLINE PLUS DOG 45-88 LBS (S62408AX) with scissors and was accidentally exposed to an unknown amount on her left hand. The pet owner is asymptomatic. No further medical information expected.
26-Jul-2019	UHAE; 19US044390; -; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 72.00 Year(s) **Weight:** 215.000 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))	26-Jul-2019*	26-Jul-2019	N/A	H-E	Human Exposure: On 26 Jul 2019, the following human exposure inquiry was reported to Safety Call International (SCI) by the pet owner for themselves, a 72 year old, 215 pound, female human of further unknown signalment. 26 Jul 2019: The pet owner applied the FRONTLINE PLUS CATS (M41702AW) to her cats and was accidentally exposed to an unknown amount on her fingers. The pet owner wiped the area with a tissue, and approximately 15 minutes after exposure she washed her hands and sprayed alcohol on her skin. She is asymptomatic. No further medical information expected.
31-Jul-2019	UHAE; 19US045170; CA; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 20.00 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))	31-Jul-2019	31-Jul-2019	N/A	H-E	Human Exposure: On 31 Jul 2019, the following event was reported by a pet owner to Safety Call International (SCI) for herself, a 20-64 year old adult female. 31 Jul 2019: While applying FRONTLINE PLUS CATS (Lot Unknown, Package Unavailable) to her cat, it moved and some of the product got on her hands. She washed them and is asymptomatic. No further medical information expected.
02-Aug-2019	UHAE; 19US046066; CA; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 79.00 Year(s) **Weight:** 158 Pounds	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products	02-Aug-2019	02-Aug-2019	0 Day(s)	H-D	Human Exposure: On 2 Aug 2019, the following event was reported by a pet owner to Safety Call International (SCI) for herself, a 79 year old, 158 lb, female. 2 Aug 2019: The pet owner was applying FRONTLINE PLUS DOG 5-22 LBS (S60810RX) to her dog when some of the product splashed into her eye. She immediately rinsed with cold water and then an eye wash twice. She is slightly irritated at this time and pale pink, but is improving.

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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: Ophthalmic **Was the product used ok?:** No (Human exposure (Off label use))					No further medical information expected. UPDATE 6 Aug 2019: SCI attempted to contact the reporter and the unknown answering party stated the contact information was incorrect. No further medical information expected.
05-Aug-2019	UHAE; 19US046155; IN; U.S.A	**Sex:** M **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 (Human exposure (Off label use))	27-Jul-2019	01-Aug-2019*	5 Day(s)	H-D	Human Exposure: On 5 Aug 2019, the following event was reported by a pet owner to Safety Call International (SCI) for himself, a 65 year old, 212 lb male, and his grandson, a 40 lb, 5 year old male. 27 Jul 2019: The pet owner applied FRONTLINE PLUS DOG 45-88 LBS (Lot Unknown) to his dog, and he and his grandson have been petting the dog since. 1 Aug 2019: The grandson developed vomiting and diarrhea. 2 Aug 2019: The reporter also developed vomiting and diarrhea. No ingestion of the product occurred. No further medical information expected.
05-Aug-2019	UHAE; 19US046271; GA; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** 82.00 Year(s) **Weight:** 152 Pounds	-	-	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** - **Was the product used ok?:** -	N/A	N/A	N/A	H-E	Human Exposure: 5-Aug-2019 Safety Call International (SCI) received a phone call stating reporters 82 year old mother cut FRONTLINE PLUS CATS (no serial provided) open to put on the cat and it splashed on her face. She denied any of the product going into her eyes, but since she is in the early stages of dementia she was worried that patient wouldn't know. The patient washed off her face with soap and water and rinsed the eye just in case. She has remained asymptomatic. No further medical information expected. 12-Aug-2019 Multiple attempts made by SCI for follow up with no response. No further medical information expected.
06-Aug-2019	UHAE; 19US046672; FL; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 68.00 Year(s) **Weight:** 180.000 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))	06-Aug-2019	06-Aug-2019	N/A	H-E	Human Exposure: On 6 Aug 2019, the following event was reported by a pet owner to Safety Call International (SCI) for herself, a 68 year old, 180 lb female. 6 Aug 2019: The pet owner opened the FRONTLINE PLUS DOG 45-88 LBS (S61202AX) and got some of the product on her right index and middle finger. She immediately washed with soap and water and is asymptomatic. No further medical information expected.
07-Aug-2019	UHAE; 19US046932; NY; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 70.00 Year(s) **Weight:** 180 Pounds	1	-	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products**	07-Aug-2019	N/A	N/A	H-E	Human Exposure: 7-Aug-2019 Safety Call International reported the following event with an animal owner 70 year old, 180 lb female. 7-Aug-2019 Caller states she applied FRONTLINE PLUS DOG 5-22 (S61006AL)to her dog about 1 hour prior to the call. During the application she got some of the product on her hands. She

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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
						used: no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure (Off label use))					rinsed and washed for a few minutes. She then read the label and continued rinsing. She has rinsed for 10-15 minutes. She remains asymptomatic. No further medical information expected.
09-Aug-2019	UHAE; 19US047635; NC; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 77.00 Year(s) **Weight:** 150.000 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))	09-Aug-2019	09-Aug-2019	N/A	H-E	Human Exposure: On 9 Aug 2019, the following event was reported by a pet owner to Safety Call International (SCI) for herself, a 77 year old, 150 lb female. 9 Aug 2019: Caller states about 20 minutes prior to call she was applying the FRONTLINE PLUS DOG 5-22 LBS (M62902AL) (Invalid lot) to her dog and she got 3/4 of the tube got onto her left hand. She washed with soap and water and then has been rinsing. She is asymptomatic. No further medical information expected.
09-Aug-2019	UHAE; 19US047712; -; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 37.00 Year(s) **Weight:** 140 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))	08-Aug-2019*	08-Aug-2019	N/A	H-E	Human Exposure: On 8 Aug 2019, the following human exposure was reported to Safety Call International (SCI) by the pet owner for themselves, a 37 year old, 140 pound, female of further unknown signalment. 8 Aug 2019: The pet owner attempted to open the FRONTLINE PLUS DOG 5-22 LBS (P62719) with scissors and was exposed to an unknown volume on her forearm. She washed the area. The pet owner is asymptomatic. No further medical information available.
14-Aug-2019	UHAE; 19US048575; MA; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** 34.00 Year(s) **Weight:** 168.000 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))	14-Aug-2019*	N/A	N/A	H-E	Human Exposure: On 26 Nov 2018, the following human exposure was reported to Safety Call International (SCI) by the pet owner for her son, a 34 year old, 168 pound, male human of further unknown signalment. 14 Aug 2019: The patient was accidentally exposed to an unknown amount of FRONTLINE TOP SPOT FOR CATS (S40601AX) on his fingertips. He rinsed his hands for about 20 minutes. The patient is asymptomatic. No further medical information is expected.
15-Aug-2019	UHAE;	**Sex:** F	1	0	0	**Product used:**	15-Aug-2019	15-Aug-2019	N/A	H-E	Human Exposure: On 15 Aug 2019, the following event was

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*indicates Approximate date or weight

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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
	19US048894; CO; U.S.A	**Sex qualifier:** Unknown**Age:** 62.00 Year(s) **Weight:** 120.000 Pounds				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))					reported by a pet owner to Safety Call International (SCI) for herself, a 62 year old, 120 lb female. 15 Aug 2019: The pet owner applied FRONTLINE PLUS DOG 45-88 LBS (S63106) to her dog and her hand slipped onto the area that was treated. She has been washing her hands and asymptomatic. No further medical information expected.
15-Aug-2019	UHAE; 19US049112; CA; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** 52.00 Year(s) **Weight:** 145 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))	15-Aug-2019	15-Aug-2019	0 Day(s)	H-D	Human Exposure: On 15 Aug 2019, the following human exposure was reported to Safety Call International by the pet owner for herself, a 52 year old, 145 pound, non-pregnant and non-lactating female. 15 Aug 2019: The patient got a small amount (exact volume unknown) of FRONTLINE PLUS (lot number unknown, package unavailable) (product unsubstantiated) on her left index finger which had a cut. The patient experienced a burning sensation for 1-2 minutes. She immediately washed her hands for 10 seconds. She did not feel well and slept for an hour. At the time of the report, the patient was awake and asymptomatic. It was noted that the patient has type 1 diabetes, high cholesterol, and hypertension. No further medical information expected.
16-Aug-2019	UHAE; 19US049270; OH; 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))	15-Aug-2019	N/A	0 Day(s)	H-E	Product Quality: On 16 Aug 2019, the pet owner reported the following product quality issue with 1 dose out of an 8 pack of FRONTLINE PLUS DOG 23-44 LBS (S60814AX). When applying the last dose in the box, the product did not come out of the tip, but came out the side of the package, all over the pet owner's hands. Photograph and product return are not expected, since it was already discarded. No further information expected. Human Exposure: On 16 Aug 2019, the pet owner reported the following event for himself, a male of unknown signalment. 15 Aug 2019: The pet owner went to apply FRONTLINE PLUS DOG 23-44 LBS (S60814AX) and the product came out of the side of the package and got on the owner's hands. He is asymptomatic and washed his hands. Reporter declined providing further information. No further medical information expected.
19-Aug-2019	UHAE; 19US049716; CA; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 53.00 Year(s) **Weight:** Unknown	-	-	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used**	19-Aug-2019	N/A	N/A	H-E	Human Exposure:On 19 August 2019, the following inquiry was reported to Safety Call International (SCI) by an unknown weight, 53 year old, female pet owner had an exposure with FRONTLINE PLUS DOG 5-22 LBS (S62405AX). 19 August 2019: A caller reported that she got a small amount of FRONTLINE PLUS DOG 5-22 LBS on one finger, about 20 minutes before this call, when she was applying the product to her pets. She reports that she washed briefly, but a few minutes later, read the product package where it recommended 10 minutes of washing. She washed her hands, again, with a soap called Method and completed the 10-minute wash. Caller is asymptomatic at this time, but is calling only because the package recommended calling

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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))					the company if any product gets on the skin. No other medical information is available.
20-Aug-2019	UHAE; 19US049808; AR; U.S.A	**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?:** No (Human exposure (Off label use))	13-Mar-2019*	13-Mar-2019	0 Day(s)	H-E	Product quality: On 20 Aug 2019, animal owner reported the following issue with FRONTLINE PLUS CATS (R41105AW). On 28 Feb 2019, the pet owner ordered 7 - 3 packs of FRONTLINE PLUS CATS through subscribe and save with Amazon. The seller's information states Sold by Amazon.com services Inc. The order Number is 114-706-3783-1449838. The Lot number on box states R41105AW, The blister pack lot number is R41105 and the pipette lot number is R4105 and states dogs 45-88 lbs. The order was delivered 13 Mar 2019 with each 3 pack individually wrapped and packaged. The boxes were damaged. The pet owner reached out to Amazon who advised they knew nothing about counterfeit product and advised owner to call the manufacture and offered to monitor the owners account. Product is available for return and pictures will be sent by the owner. No further information expected. Human Exposure: On 20 Aug 2019, an animal owner reported the following event to Safety Call International (SCI) for herself, a female of further unknown signalment. 13 Mar 2019: The pet owner received a package labeled as FRONTLINE PLUS CATS (R41105AW) with pipettes labeled as FRONTLINE PLUS DOG 45-88 LBS (R4105) (invalid lot) inside. The owner got an unknown amount of product on her hands. She washed her hands and remained asymptomatic. No further medical information expected.
22-Aug-2019	UHAE; 19US050499; CA; U.S.A	**Sex:** M **Sex qualifier:** -**Age:** 81.00 Year(s) **Weight:** 150 Pounds	0	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))	22-Aug-2019	N/A	N/A	H-E	Human Exposure:On 22 August 2019, the following inquiry was reported to Safety Call International (SCI) by a pet owner for FRONTLINE PLUS FOR DOGS 45-88 LBS (P62501BR). 22 August 2019: Ten minutes prior to calling SCI, the caller was completing the application of FRONTLINE PLUS FOR DOGS 45-88 LBS and then he rubbed it into the dog with his fingers. He washed his hands and is asymptomatic. No other information is available.
22-Aug-2019	UHAE; 19US050770; TX; U.S.A	**Sex:** M **Sex qualifier:** -**Age:** - **Weight:** Unknown	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Human exposure (Off label use))	19-Aug-2019	19-Aug-2019*	0 Day(s)	H-D	Human Exposure: On 22 Aug 2019, the following human exposure was reported to Safety Call International (SCI) by the owner for himself, a male of further unknown signalment. 19 Aug 2019: One pipette of FRONTLINE PLUS DOG 45-88 LBS (lot number unknown, reporter refused) was applied to three dogs. It is unknown how the owner may have came into contact with the product. Reporter indicates there are active fleas in the home and that reporter is being "eaten alive" by fleas. The reporter developed lesions all over his body. It is unknown if any treatment was sought, and the current status of the patient is unknown. It was noted that the patient believes that the product was tampered with and that is why it was not working for the dogs (see case 19US050805), but the caller refused to specify in what way he thinks the product was tampered with. No further medical information expected.

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22-Aug-2019	UHAE; 19US050802; MI; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 28.00 Year(s) **Weight:** 160.000 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))	22-Aug-2019	22-Aug-2019	0 Day(s)	H-D	Human Exposure: 22-Aug-2019 Safety Call International (SCI) reported the following event in 28 year old, 160 lb, Female. 22-Aug-2019 Animal owner reported she was applying FRONTLINE PLUS 45-88LBS (S616038X) to her pet 10 minutes ago and accidentally got the product into her right eye. She does not wear contacts. She is currently experiencing a headache, redness and ocular irritation. She has rinsed her eyes out with water. No further information at this time. UPDATE: 27-Aug-2019 SCI attempted multiple follow ups with no response. No further medical information expected.
30-Aug-2019	UHAE; 19US052209; -; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 79.00 Year(s) **Weight:** 170.000 Pounds	1	-	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))	30-Aug-2019	N/A	N/A	H-E	Human Exposure: 30-Aug-2019 Safety Call International (SCI) reported the following event in 79 year old female. 30-Aug-2019 Animal owner reported about 30 minutes ago in her home, she was trying to open FRONTLINE PLUS for DOGS 89-132 LBS (S62006RX) packaging that was difficult to open. She ended up trying to cut it open with scissors and got about one third of product all over both of her hands. She states she washed her hands with soap and water then applied vinegar and washed hands again. She is asymptomatic. No further medical information expected.
30-Aug-2019	UHAE; 19US052273; -; 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 (Intentional)	30-Aug-2019	30-Aug-2019	0 Day(s)	H-D	Human Exposure: 30-Aug-2019 Safety Call International (SCI) reported the following event in a 30 year old female. 30-Aug-2019 Animal owner reports she applied FRONTLINE PLUS DOG 5-22 LBS (no serial provided) to her dog 10 minutes ago. She used her right hand pointer finger to rub the product into her dog's skin. She then scrubbed under her nails with soap and water. Just before the call she developed a tingly feeling from her pointer finger up to her forearm. No further information expected. UPDATE: 5-Sep-2019 Per SCI follow up the reporter washed the area as advised and symptoms resolved several hours later that evening 30-Aug-2019. No further medical information expected.
04-Sep-2019	UHAE; 19US052896; PA; U.S.A	**Sex:** F **Sex qualifier:** Pregnant**Age:** 25.00 Year(s) **Weight:** 115 Pounds	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used**	04-Sep-2019	04-Sep-2019	0 Day(s)	H-D	Human Exposure: 4-Sep-2019 Safety Call International (SCI) reported the following event in 25 year old, 115 pound, pregnant female. 4-Sep-2019 Caller reports when she popped the tab on the product FRONTLINE PLUS CATS (S40606AW) it shot into her right eye. She has rinsed her eye for about 10 minutes. Initially is was red and irritated not it just does not feel normal. Her primary concern is that she is 13 weeks pregnant. UPDATE 16 Sep 2019: SCI left several messages with the reporter without response. 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?: No (Human exposure (Off label use))					
09-Sep-2019	UHAE; 19US053625; -; U.S.A	**Sex:** F **Sex qualifier:** -**Age:** 61.00 Year(s) **Weight:** 128.000 Pounds	1	-	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))	09-Sep-2019	N/A	N/A	H-E	Human Exposure: 10-Sep-2019 Safety Call International (SCI) reported the following event in 61 year old, 128 pound, adult female. 9-Sep-2019 Patient states 30 minutes ago she got FRONTLINE PLUS DOG 23-44 LBS (no serial provided) on her hands. She has washed her hands and is asymptomatic. No further medical information expected.
11-Sep-2019	UHAE; 19US054399; MI; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 3.00 Year(s) **Weight:** 40.000 Pounds	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Human exposure (Off label use))	11-Sep-2019*	11-Sep-2019	N/A	H-E	Human Exposure: On 11 Sep 2019, the following human exposure was reported to Safety Call International (SCI) by the pet owner his daughter, a 3 year old, 40 pound, female human of further unknown signalment. 11 Sep 2019: The reporter observed an empty package of FRONTLINE PLUS DOG (lot number unknown) (product unsubstantiated), and believes the patient was exposed to the FRONTLINE. The patient is asymptomatic. No further medical information expected.
08-Sep-2019	UHAE; 19US055514; -; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	0	0	**Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Human exposure (Off label use))	07-Sep-2019*	07-Sep-2019	N/A	H-E	Human exposure: On 08 Sep 2019, the following event was reported to Safety Call International (SCI) by the animal owner for himself, a male of unknown signalment. 07 Sep 2019: The animal owner applied an unknown amount of FRONTLINE SPRAY (M30401A) to his owner legs. He is asymptomatic and declined provided further information about his exposure. His dog also has a case, 19US053918. No further medical information expected.
18-Sep-2019	UHAE; 19US056087; FL; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 19.00 Year(s) **Weight:** 103.000 Pounds	1	1	0	**Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the**	18-Sep-2019	18-Sep-2019	0 Day(s)	H-E	Human Exposure: On 18 Sep 2019, the following human exposure was reported by a pet owner to Safety Call International (SCI) for herself, a 103 lb, 19 year old female. 18 Sep 2019: The pet owner was putting FRONTLINE PLUS CATS (S40210BW) on her cat about 15 minutes before the call and she got a little of it on one hand. Caller became concerned and washed her hands vigorously in hot water with soap. She reports that her fingers felt like they were tingling. No further medical information expected. UPDATE 24 September 2019: SCI attempted a call back to the patient and there was no answer or way to leave a voicemail

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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))					message. No other information is available. UPDATE 26 September 2019: SCI attempted a call back to the patient and there was no answer or way to leave a voicemail message. No other information is available. UPDATE 30 Sep 2019: SCI attempted a call back to the patient and there was no answer or way to leave a voicemail message. No further medical information expected.
19-Sep-2019	UHAE; 19US056110; NE; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 38.00 Year(s) **Weight:** 150 Pounds	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))	19-Sep-2019	N/A	N/A	H-E	Human Exposure 19-Sep-2019: Safety Call International (SCI) reported the following event in a 38 year old, 150 pound woman. 19-Sep-2019 Human patient stated she got product on her hand when applying FRONTLINE PLUS CATS (S41003) to her pet 30 minutes prior to call. She washed with soap and water and remains asymptomatic. No further information expected.
19-Sep-2019	UHAE; 19US056155; NY; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 50.00 Year(s) **Weight:** 165 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-Sep-2019	19-Sep-2019	0 Day(s)	H-D	Human Exposure: On 19 September 2019, the following event was reported to Safety Call International (SCI) by a 50 year old, 165 pound, female pet owner that was exposed to FRONTLINE PLUS DOG 5-22 LBS (lot unknown). 19 September 2019: Ten minutes prior to calling SCI, the caller got some FRONTLINE PLUS DOG 5-22 LBS on her right hand as it squirted out while she was opening the package. At first, she had some burning/stinging sensation and she washed her hands twice with soap and water. She no longer has any symptoms at the time of the call to SCI. The patient has a medical history of a soy allergy, diabetes type 1, heart disease, kidney transplant X2, hypertension and high cholesterol. No other information is available.
20-Sep-2019	UHAE; 19US056366; -; 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:** - **Was the product used ok?:** No (Human exposure (Off label use))	20-Sep-2019	N/A	N/A	H-E	Human Exposure 20-Sep-2019: Safety Call International reported the follwoing event in female of unknown signalment. 20-Sep-2019 Caller states she had gottenFRONTLINE PLUS DOG 5-22 (no serial provided) on her fingers when applying to her dog. She didn't realize it at first and it was a couple of minutes later that she rinsed with soap and water for less than 20 minutes. Caller was very impatient and refused to provide any further case details and declined follow up. No further information expected.
25-Sep-2019	UHAE; 19US057133; OH; U.S.A	**Sex:** M **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown	1	0	0	**Product used:** FIPRONIL 10%/S METHOPRENE	25-Sep-2019	25-Sep-2019	N/A	H-E	Product Quality: On 25 Sep 2019, the pet owner reported the following product quality issue with 1 dose out of 3 pack of FRONTLINE PLUS CATS (S40606AW). Pet owner tried to open product and had trouble tearing two labels apart, took a sharp

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						12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure (Off label use))					object to vial to try and open and spilled the vial on hands. No product return of expected as owner has discarded it. No further information expected. Human Exposure: On 25 Sep 2019, the following human exposure was reported by a pet owner for himself, a male of unknown signalment. 25 Sep 2019: The pet owner spilled an unknown amount of FRONTLINE PLUS CATS (S40606AW) on his hands. He washed them and is asymptomatic. No other details are known as the owner declined to make a report. No further medical information expected.
26-Sep-2019	UHAE; 19US057734; OH; U.S.A	**Sex:** F **Sex qualifier:** Unknown**Age:** 68.00 Year(s) **Weight:** 200 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))	26-Sep-2019	26-Sep-2019	0 Day(s)	H-D	Human Exposure: On 26 September 2019, the following event was reported to Safety Call International (SCI) by a 68 year old, 200 pound female that was exposed to FRONTLINE PLUS CATS (unknown). 26 September 2019: The caller reported to SCI that she ordered the FRONTLINE PLUS CATS from Amazon. She received the delivery on 26 September 2019 and all of the products she ordered came in one box. She states the FRONTLINE PLUS CATS was broken up (details of this are unknown) and she picked the product up with her bare hands, this occurred approximately 5 minutes prior to calling SCI. The caller reported that she must have touched her mouth and her lips after touching the FRONTLINE PLUS CATS because she began to have a tingling pin prick sensation to her hands and lips. She described that this sensation felt like when your hands fall asleep. She states that she also has a bad taste in her mouth. She has rinsed her mouth, brushed her teeth, gargled with Coke, and washed her hands with soap and water but her symptoms were persisting. This caller has a history of Lupus, Type 2 diabetes, coronary heart disease, high blood pressure, and congestive heart failure. No other information is available. UPDATE: 3-Oct-2019 Multiple attempts made by SCI to obtain follow up details, no response. No further medical information expected.
30-Sep-2019	UHAE; 19US058105; MI; 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))	30-Sep-2019	N/A	N/A	H-E	Human Exposure: On 30 September 2019, the following inquiry was reported to Safety Call International (SCI) by female of unknown signalment that was exposed to FRONTLINE PLUS CATS (lot unknown). 30 September 2019: Caller states that she applied FRONTLINE PLUS CATS on her cat today and she got some on her hands approximately 2-3 hours prior to calling SCI. The caller washed her hands with hands with soap and water. She is asymptomatic, but reports that she has a louse infestation on herself and an ongoing rash that was present prior to the exposure to FRONTLINE PLUS CATS. No other information is available.

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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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19AU000937
	Address APVMA PO Box 6182 Kingston ACT, 2604 Australia		Address --UNKNOWN--	
	Phone # 0262104903		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 05-20-2019	Date registrant became aware of incident. 09-06-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 54523	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 S	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? 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 : 12-Sep-2019 at 01:27

Internal ID # 19AU000937

Brief description of incident circumstances

As reported by the regulatory authority, a male Maltese cross Poodle born on 14 FEB 2019 was administered a Companion C3 vaccine on 26 APR 2019. On 9 MAY 2019 the puppy was administered an allwormer (Drontal) and had flea control applied (FRONTLINE PLUS). 14 MAY 2019 – The puppy had a microchip implanted. 18 MAY 2019 – The puppy came into the possession of a new owner. 20 MAY 2019 – The puppy was vomiting. 21 MAY 2019 – The puppy was anorexic, weak and vomiting approximately once every 30 minutes. 22 MAY 2019 – In the afternoon the puppy was presented to a vet clinic. Clinical examination revealed a weight of 1.06 kg, extremely weak, recumbent, unable to right self, head held backward, pale mucous membranes, temperature 37.3 C, and a congenital abnormality of the prepuce. A CPV faecal antigen test was negative. The puppy was assessed as being severely dehydrated, in shock and ill-thrift. The puppy was hospitalised, warmed and placed on IV fluids. A blood test revealed hypoglycaemia and the puppy was treated with multiple SC injections of glucose. Urinalysis revealed: USG: 1.025, Urobilinogen: normal, Protein: +++++, pH: 6, Blood: -ve, Ketone: 160, Bilirubin: -ve, Glucose: -ve. Blood tests and blood gases revealed: PCV/TP: 33/30, low blood pH and pCO2, high pO2, and decreased potassium, sodium, chloride, bicarbonate and haematocrit. In the evening the puppy ate a small amount of food and was able to stand. An injection of antibiotic (amoxicillin clav) was administered and IV fluids continued. 23 MAY 2019 – The puppy was still in hospital. A blood smear revealed mild anisocytosis, adequate platelets and approximately 10% of the neutrophils were band neutrophils. Clinical examination revealed very pale mucous membranes, a heart rate of 200+ bpm, and a temperature of 38.2 C, but the puppy was brighter, eating well and urinating. Blood tests revealed: Blood gas pH 7.175 (7.3 -7.4), K+ 3.8, Na+ 134, Cl 109, glucose 2.7, SBE -17.8, Hct 31.5%, PCV/TP 35/31. Blood glucose monitoring throughout the day showed: 8am: 2.7 mmol, 11am: 1.9 mmol, 1pm: 2.1 mmol, 2pm: 3.4 mmol, 3.30pm: 4.8 mmol. The puppy was treated with syringe feeding of a/d diet, oral antibiotics (Noroclav) and oral fenbendazole. In the afternoon the puppy was discharged home with ongoing feeding every 2 hours and oral antibiotics (Noroclav). 24 MAY 2019 – The puppy's 3.6. The owner stated that the puppy was doing well at home and was still being syringe fed. 26 MAY 2019 – The puppy re-presented to the vet clinic due to multiple vomits the previous night, and this morning was recumbent and non-responsive. Clinical examination revealed the puppy to be dull, non-ambulatory, non-responsive, temperature too low to register and diarrhoea on thermometer. An IV catheter was placed and glucose administered IV. Further diagnostic workup was offered but was declined by the owner and the puppy was euthanased. 29 MAY 2019 – A post-mortem (gross examination only) was performed at the vet clinic and no major abnormalities were found. No further information expected. This is the extent of the information available.

Demographic information: Age: 3 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: 11 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) IV fluids, glucose,	List signs/symptoms/adverse effects Emesis Anorexia Lethargy Recumbency Pale mucous membrane Hypothermia Birth defect Dehydration Circulatory shock Poor feed conversion Hypoglycaemia Proteinuria Acidosis Hypokalaemia Hyponatremia *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: Unknown			
Human severity category			

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

Internal ID #
19AU000937

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

Hypochloraemia

Anaemia NOS

Acid-base disorder

Disorder of red blood cell NOS

Tachycardia

Loss of consciousness

Diarrhoea

Death

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19DE000664
	Address Mönchengladbach 41189 Germany		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 07-16-2019	Date registrant became aware of incident. 07-20-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 400729.00.00	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 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 : 26-Jul-2019 at 08:58

Internal ID # 19DE000664

Brief description of incident circumstances

As reported by the owner 2 crossbreed (Maine Coon/European) kittens, 12 weeks old, weighing 945 g and 985 g, respectively, were brought in a new household (Maine Coon cattery) without any vaccination at about 9 Jul 2019. They were treated topically in the neck with 1 dose of Frontline Combo Spot-on Cats (off-label use: kittens are too light) on about 12 Jul 2019 by the animal owner. Approx. 4 days after the treatment the male kitten showed anorexia, apathy, and vomiting. The very next day (17 Jul 2019) he also had diarrhea and was brought to a vet. There an antibiotic was administered (no more details available) and the kitten received electrolytes. The full blood analysis showed a severe leukopenia but no other findings. On 18 Jul 2019 he received antibiotic treatment again, but the general condition worsened and on 19 Jul 2019 the male kitten died. No necropsy. Since 19 Jul 2019 the female kitten also showed anorexia, increasing apathy, and vomiting, no defecation. On 24 Jul 2019 she was apathic and had diarrhea, on 25 Jul 2019 she ate by herself and the feces were firmer. The kitten was treated the last days with some penicillin p.o. (no further details) and some stool sample was send to a lab (giarida negative). Other cats from the same breeder/owner are without similar symptoms and were not treated with Frontline or Frontline Combo recently, but have received these products in the past without any problems.
Additional information: the new owner also has a farm with horses and stray cats.

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: 12 Week(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: 4 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Antibiotics and	List signs/symptoms/adverse effects Anorexia Lethargy Emesis Diarrhoea Intestinal stasis Death Leucopenia		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: 945 - 985 gms			
Human severity category			

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

Internal ID #

19DE000664

* approximate

Version : 26-Jul-2019 at 08:58

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 A FAB...	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19FR000809
	Address 31 France		Address --UNKNOWN--	
	Phone #		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 06-23-2019	Date registrant became aware of incident. 07-04-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) FR/V/8481982 4/1996	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 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? 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 : 11-Jul-2019 at 16:31

Internal ID # 19FR000809

Brief description of incident circumstances

FR-ANMV-19 CPVL 00874: T0: two cats were applied with FRONTLINE SPOT ON CHAT. T+6h: they successively displayed drunken gait, ataxia, falling, then apathy. T+9h: the first cat was presented to emergency clinic (vet college). T+11h: the second cat was also examined at same emergency clinic. They were in polypnoea, and diagnosed with acute renal failure. The cats were washed and administered with fluids therapy, antiemetic, manitol, anticonvulsivant, intralipids. Without improvement, both were euthanasied. No necropsy performed. Note: product
24 hours
Duration of reaction (precision): approx.15 hours. Reason for treatment: Preventive.
Treatment of SAR: fluids therapy, antiemetic, manitol, anticonvulsivant, intralipids, washing.
Outcome of SAR: Unfavorable

Demographic information: Age: 10 - 11.5 Year(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) Fuids therapy,	List signs/symptoms/adverse effects Ataxia Ataxia Ataxia Lethargy Renal insufficiency Death Tachypnoea		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: 1 pipette per cat; Expose duration: 0 Day(s) Patient weight: 3-4 kg			
Human severity category			

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

Internal ID #
19FR000809

* approximate

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 Azusa Dohi	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19JP000162
	Address Nerima Animal Care Center, Hondo Animal Hospital Hospital Kasuga building 1F Kasugacho 179-0074, Japan		Address --UNKNOWN--	
	Phone # 03-5971-3033		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-10-2019	Date registrant became aware of incident. 08-20-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 15 Sho-An 1979	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 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)).	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 : 27-Aug-2019 at 03:33

Internal ID # 19JP000162

Brief description of incident circumstances

As reported by the attending veterinarian, on 10 Aug 2019, Frontline Plus Cat (Lot number and Expiry date: Unknown, Topical, 1 pipette) was prescribed and administered to a 13 year old, 5 kg, male, neutered mix cat at another animal hospital. The cat may have licked the application site. The cat subsequently developed loss of vigor, anorexia and tachypnea, and was crouching. The cat was brought to the hospital due to vomiting for 3 consecutive days. Although vomiting had stopped on the fourth day, the cat still had loss of vigor, anorexia and tachypnea. On 15 Aug 2019, a blood test and an X-ray examination were performed and treatment with drip infusion was given to the cat at another hospital. (It is unknown whether this was the hospital that had prescribed the product.) Although the white blood cell count was 19000 and the K level was a little low, there were no abnormalities. The X-ray also detected no abnormalities. On the next day, 16 Aug 2019, the cat was brought to the hospital. Body temperature was 36.2 degrees Celsius in the morning. The cat was breathing abdominally with his mouth open. Clouding of consciousness was observed and the condition deteriorated. At 5 PM, body temperature dropped to 33.6 degrees Celsius. At 6 PM, the cat vomited and died. Since the owner wrote in the medical questionnaire at the first visit that the cat was fed renal food, the cat may have had some kidney problems.

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: 0 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Drip infusion(saline	List signs/symptoms/adverse effects Anorexia Lethargy Tachypnoea Emesis Leucocytosis NOS Hypothermia Dyspnoea Impaired consciousness		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 kg			
Human severity category			

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

Internal ID #

19JP000162

Version : 27-Aug-2019 at 03:33

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 Unknown Unknown	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19JP000196
	Address Izumi Osaka Japan		Address --UNKNOWN--	
	Phone #		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 07-10-2019	Date registrant became aware of incident. 09-12-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 15 Sho-An 1977	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 M	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)).	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 : 18-Oct-2019 at 05:48

ED_005739D_00014390-00890

Internal ID # 19JP000196

Brief description of incident circumstances

As reported by the owner, on 08 Jul 2019, Frontline Plus (Lot number: unknown, Expiry date: unknown, Topical, dosage unknown) was administered to an 11 years and 8 months old, female, Bichon frise (BW: unknown, Reproductive status: unknown). The dog developed anorexia and loss of vigor two days later and was immediately brought to the hospital. According to the results of a blood test, an elevated level of hepatic function was observed. The dog had experienced elevated hepatic level several times before. Usually, the dog followed the course by displaying symptoms of vomiting at first, and then a treatment with intravenous drip and administration of drugs at the hospital was given for about 1 week and the symptoms resolved. However, the symptoms did not resolve this time and the dog died on 27 Aug 2019. The dog had a portosystemic shunt surgery at the age of 1 in the past. Although the dog developed transient convulsion after the surgery and was in a critical state, resolved recovery was achieved after a home care. Since the dog had good appetite and vigor prior to administration of Frontline Plus, the owner considers that the administration of Frontline Plus was a strain on the dog's liver and caused the death. UPDATE 16 Oct 2019: Following internal review, previously reported death was added to the VeDDRA coding.

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: 11.7 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: 2 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) drip infusion and	List signs/symptoms/adverse effects Anorexia Lethargy Elevated liver enzymes 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 #

19JP000196

Version : 18-Oct-2019 at 05:48

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 Kanichi Yamada	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19JP000198
	Address Yamada Animal Hospital 4-12-6, Kyuden, Setagaya, Tokyo 157-0064 Japan		Address --UNKNOWN--	
	Phone # 03-3309-1719		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-14-2019	Date registrant became aware of incident. 09-17-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 15 Sho-An 1979	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 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? 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)).	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 : 24-Sep-2019 at 09:29

Internal ID # 19JP000198

Brief description of incident circumstances

As reported by the attending veterinarian, in the morning on 14 Sep 2019, the animal hospital received a phone call from the animal owner. Frontline Plus Cat (Lot number and Expiry date: Unknown, Topical, 1 pipette) was administered to a 6 years old, 5 kg, female, spayed, Japanese cat by the owner. After about 1 hour, the cat collapsed and fell off the couch. After about 30 minutes, the cat was put in a carrier and was brought to the hospital. The director of the hospital examined the cat, and he thought that the carrier looked a little narrow and the airway was compressed. He saw the cat still breathing, but when he saw the animal again after a quick glance at a medical record, the animal was dead. The owner felt that the cat was not breathing on the way to the hospital from home. In spite of immediate cardiopulmonary resuscitation, intubation, intravenous administration of diluted Bosmin injection, etc. for an emergency, the cat died.

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: 6 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 Month(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Cardiopulmonary	List signs/symptoms/adverse effects Collapse 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: 3 Month(s) 2 Week(s) Patient weight: 5 kg			
Human severity category			

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

Internal ID #

19JP000198

* approximate

Version : 24-Sep-2019 at 09:29

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19NL000127
	Address Netherlands		Address --UNKNOWN--	
	Phone #		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 07-18-2019	Date registrant became aware of incident. 07-16-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) REG NL 8940	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 HOND M	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)).	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 : 19-Jul-2019 at 17:35

Internal ID # 19NL000127

Brief description of incident circumstances

As reported by pet owner via social media, 1 male dog, 6 years old, of unknown weight and unknown reproductive status received FRONTLINE of unknown lot and use by date, unsubstantiated which exact product or strength, by the dog's owner at unknown date. Dose and application frequency unknown. Owner reports that unknown time after application dog died. Unknown if veterinarian has been consulted. Owner reports that blood of the dog was sent to Utrecht and appears that the dog has died due to an unsubstantiated substance from FRONTLINE. Owner is grieving and unwilling to substantiate the information, provide additional information or laboratory/autopsy reports. Owner received the product from a pound where the dog used to be housed, they had surplus pipets, which the owner was instructed to use every 5 to 6 weeks.

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: 6 Year(s) - Sex : Male Occupation (if relevant)	Exposure route:	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-- Expose duration: Patient weight: Unknown			
Human severity category			

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

Internal ID #

19NL000127

Version : 19-Jul-2019 at 17:35

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19SE000162
	Address Sweden		Address --UNKNOWN--	
	Phone #		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 07-14-2019	Date registrant became aware of incident. 08-27-2019	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 DOG	A.I. (s)	A.I. (s)
	Product 1 name FRONTLINE SPOT-ON VET DOGS S 100 MG/ML SPOT ON	Product 2 name	Product 3 name
	Exposed to concentrate prior to dilution ? No	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)).	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 : 27-Aug-2019 at 12:04

Internal ID # 19SE000162

Brief description of incident circumstances

Mother / offspring SAE case split in two cases. The case was initially reported with both mother and offspring in case 19SE000122. After split of the case, the mother will be reported in the case 19SE000122 and the offspring will be reported in the case 19SE000162. The cases are linked in the MAH database.
As reported by the animal owner, a dog, female, pregnant (rough coated miniature dachshund, 6 kg, date of birth 18 JUN 2012, healthy) received FRONTLINE VET SPOT-ON FOR DOGS up to 10 kg (size S) (LOT S20901AX, EXP JUN 2021, valid) topically applied to the area between the shoulder blades, 1 dose given by the owner every 4 weeks on 06 MAY 2019, 03 JUN 2019 and 01 JUL 2019, as treatment against dandruff mites (off-label use, not listed in the local labelling). The owner described that the dog had a bleeding approximately at the same time as product administration or a few days later (not specified after which of the product administrations). The reaction was not treated. The dog was mated on 12 MAY 2019 and gave birth to two pups on 14 JUL 2019. According to the owner both pups were malformatted with, among other things, missing ears (not further specified), and had to be euthanised (date not specified). The owner states that no veterinarian has been involved.
No information available on the relatedness and inbreeding of this specific mating. Follow up information: As reported by the owner, the bitch had had three litters prior to this one. The owner had used FRONTLINE in the kennel before and also on this bitch. The puppies were born without open ear canal and missing ears, they also had cleft palate and cleft nose. The owner reported this was the first time in 30 years she had seen malmformed puppies.

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: 0 Day(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: 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 Death Birth defect Congenital digestive tract disorder Congenital ear disorder NOS		If lab tests were performed, list test names and results(If available submit report). None reported
Exposure data: Amount of pesticide: Mother - pregnancy exposure Expose duration: 8 Week(s) Patient weight: Unknown			
Human severity category			

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

Internal ID #

19SE000162

Version : 27-Aug-2019 at 12:04

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19UK002088
	Address United Kingdom		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 06-30-2019	Date registrant became aware of incident. 07-05-2019	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)).	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 : 17-Jul-2019 at 11:29

Internal ID # 19UK002088

Brief description of incident circumstances

As reported by the animal owner, Winks, a feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, further details unknown) for an unknown indication. The animal owner reports that they have been really pleased with the service but that they are going to try another treatment for their animals due to financial reasons and unfortunately one of their cats, Winks, passed away a few weeks ago.

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:	
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			

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

Internal ID #

19UK002088

Version : 17-Jul-2019 at 11:29

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19UK002264
	Address United Kingdom		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 07-24-2019	Date registrant became aware of incident. 07-18-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) Vm 08327/4269	EPA Registration # (Product 2) Vm 08327/4132	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s) FIPRONIL SPOT ON DOG	A.I. (s)
	Product 1 name FRONTLINE PLUS SPOT ON DOGS M	Product 2 name FRONTLINE SPOT ON DOG M	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)).	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 : 24-Jul-2019 at 18:37

Internal ID # 19UK002264

Brief description of incident circumstances

As reported by the animal owner, a 14.5 year old female canine (signalment otherwise unknown), was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry and details unknown) for an unknown indication. The animal owner has lots of experience with dogs, showing, working and breeding and in the past owning large kennels, and they used to use FRONTLINE (assumed FRONTLINE SPOT ON DOG M) for years successfully. The animal was recently put to sleep as had vestibular syndrome. The animal owner also has a cat that is treated with FRONTLINE PLUS and there are no fleas on the cat.

Demographic information: Age: 14.5 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 Internal ear disorder 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			

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

Internal ID #
19UK002264

Version : 24-Jul-2019 at 18:37

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19UK002557
	Address United Kingdom		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-19-2019	Date registrant became aware of incident. 08-09-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) Vm 08327/4267	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 SPOT ON 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)).	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 : 21-Aug-2019 at 12:42

Internal ID # 19UK002557

Brief description of incident circumstances

As reported by the animal owner, a female lactating feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner for an unknown indication. The animal owner reports that they put FRONTLINE PLUS on their cat, which had 5 kittens at 3 weeks old, on advice from a shop and now 4 of the kittens have died within the space of 12 hours and the fifth kitten is fighting for it's life. The animal owner doesn't think that this is a coincidence as they were all fit and healthy. They think that this is due to the product. Start date added for submission purposes only.

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 Week(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:	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death Moribund		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			

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

Internal ID #

19UK002557

Version : 21-Aug-2019 at 12:42

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19UK002599
	Address United Kingdom		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-22-2019	Date registrant became aware of incident. 08-13-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) Vm 08327/4267	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 SPOT ON 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)).	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 : 22-Aug-2019 at 14:58

Internal ID # 19UK002599

Brief description of incident circumstances

As reported by the animal owner, 2 cats (estimated, signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they have 2 FRONTLINE PLUS delivered to their house, however needs to cancel one of them as one of their cats has died. Start date of event added for submission purposes only.

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: Unknown	
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			

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

Internal ID #

19UK002599

Version : 22-Aug-2019 at 14:58

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19UK002872
	Address United Kingdom		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-30-2019	Date registrant became aware of incident. 08-29-2019	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)).	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 : 5-Sep-2019 at 10:05

Internal ID # 19UK002872

Brief description of incident circumstances

As reported by the animal owner, 2 male cats (signalment otherwise unknown) were treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, for years, for an unknown indication. The owner reported that they had been recommended that they do not use FRONTLINE or any other flea treatment other than Advocate. The owner used FRONTLINE for years on their 2 boys, who have since sadly passed away, with no problem. The owner used Advocate once and one of their 3 kittens (assumed not the same animals as referred to using FRONTLINE) had a bad reaction to it (no further information provided). Start date of event added for submission purposes only.

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: Unknown	
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			

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

Internal ID #

19UK002872

Version : 5-Sep-2019 at 10:05

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19UK003155
	Address Pets at Home Limited Epsom Avenue Stanley Green Trading Estate Handforth, Cheshire, SK9 3RN United Kingdom		Address --UNKNOWN--	
	Phone #		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 10-08-2019	Date registrant became aware of incident. 09-09-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) Vm 08327/4270	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 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? 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 : 8-Oct-2019 at 17:18

Internal ID # 19UK003155

Brief description of incident circumstances

As reported by the retail outlet staff member, a small terrier canine (signalment otherwise unknown) was administered one of the products belonging to the MAH (assumed FRONTLINE PLUS SPOT ON DOG S) (details unknown) for an unknown indication. The retail outlet staff member reported that the very upset customer called up as they feel that the product is to blame for the loss of their dog, their husband potentially losing his job and her near death. The animal owners signed up two of their other canines (signalment otherwise unknown) for FRONTLINE PLUS SPOT ON DOG L with a store and have received 3 months of treatment in this time. One of their dogs, a small terrier (never on the subscription) has apparently passed away from fleas after using the products. The fleas entered his brain and caused neurological problems. The animal owner's husband is currently suspended from his job due to having flea bites on his arms as he has to wear short sleeved shirts and his company is not happy with his appearance. The animal owner has nearly passed away from the bites, she has claimed that the bites are septic and that their doctor is visiting her at home due to this. They have had to buy new furniture for the home due to the extent of the fleas. The animal owner has also contracted Lyme Disease from a tick whilst using the product. When asked about the fleas the animal owner claimed that their pets did not have fleas when signing up to the service and this happened suddenly.The animal owner had used numerous sprays and treatments on the home. The reporter states that they haven't managed to get too much information from the animal owner as when questions began they did start to become upset and aggressive. Start date added for submission purposes only. This case is linked to 19UK003050.
UPDATE from authority 30 SEP 2019: VMD update: this has been reported as a lack of efficacy so it has been changed to LEE. Veddra added for LEE and deleted for neurological signs.

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:	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Death Lack of efficacy		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 #
19UK003155

Version : 8-Oct-2019 at 17:18

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 unknown	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US040384
	Address U.S.A		Address --UNKNOWN--	
	Phone # 412-576-4249		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 01-01-2018	Date registrant became aware of incident. 07-10-2019	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)).	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 : 19-Jul-2019 at 17:32

Internal ID # 19US040384

Brief description of incident circumstances

Suspected Adverse Event: 10 Jul 2019: An owner reported the following event in a canine of unknown signalment.
01 Dec 2017*: The owner administered one dose FRONTLINE PLUS DOGS 45-88 LBS (lot unknown, package unavailable) and HEARTGARD PLUS (136 MCG/114 MG)(lot/expiration date unknown, package unavailable) (*products weight range unsubstantiated) in unknown manners.
01 Jan 2018*: The dog died. It is unknown if this was a euthanasia or natural cause. The owner reported in passing while requesting information on expiration dates for the product. Dates approximate for reporting purposes only. No further medical information expected or 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: 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: 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 #

19US040384

* approximate

Version : 19-Jul-2019 at 17:32

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US039801
	Address Unknown U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 06-02-2019	Date registrant became aware of incident. 07-09-2019	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)).	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 : 19-Jul-2019 at 16:03

Internal ID # 19US039801

Brief description of incident circumstances

Suspected Adverse Event: On 9 Jul 2019, the pet owner reported the following event for a 14 year old female dog of further unknown signalment.
1 Jun 2019*: The patient received a dose of FRONTLINE PLUS DOG 45-88 LBS(lot and expiration unknown).
2 Jun 2019*: The patient passed away due to many unknown issues and old age, one being hip problems. It is unknown when all the problems exactly began.
Further infomration is unknown as the owner refused further inquiry. 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: 14 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: 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: 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 #

19US039801

* approximate

Version : 19-Jul-2019 at 16:03

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter) Unknown	Internal ID # 19US041314
	Address Ex. 6 PP – personal address RUSSELLVILLE AL 35653 U.S.A		Address Emergency Clinic - Jones Area Vet Emergency U.S.A	
	Phone # Ex. 6 PP – personal phone		Phone # 256-740-4800	
	Incident Status: New If update,include date of original submission	Location and date of incident. 06-20-2019	Date registrant became aware of incident. 07-15-2019	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)).	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 : 29-Jul-2019 at 14:58

Internal ID # 19US041314

Brief description of incident circumstances

Suspected Adverse event: On 15 Jul 2019, the owner reported the following event for Thor, 2 year old, 10 pound, male neutered, Domestic Shorthair.
20 June 2019: One vial FRONTLINE PLUS CATS (S41003AW) was applied topically in between the shoulder blades in one location.
Within 24 hours the cat became extremely lethargic, stumbling around, and not eating/drinking.
21 Jun 2019: The pet was presented to the emergency clinic. The cat was given treatment with IV fluids, Interferon alpha, and B-12 Injections.
22 Jun 2019: The cat passed away at the clinic.
This is the first dose of FRONTLINE applied to the cat. There are 5 other cats within the home that experienced a lack of efficacy while using the product, 19US041315. No further medical information expected 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: 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) IV fluids, Interferon	List signs/symptoms/adverse effects Lethargy Ataxia 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: 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 #

19US041314

Version : 29-Jul-2019 at 14:58

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter) Dr Andrew CLEVELAND	Internal ID # 19US041759
	Address Ex. 6 PP – personal address PHILADELPHIA PA 19139 U.S.A		Address HIGHLAND PARK ANIMAL HOSPITAL 137 S STATE RD UPPER DARBY PA, 19082 U.S.A	
	Phone # Ex. 6 PP – personal phone		Phone # 610-352-2020	

	Incident Status: New If update,include date of original submission	Location and date of incident. 07-14-2019	Date registrant became aware of incident. 07-16-2019	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)).	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 : 30-Jul-2019 at 15:35

Internal ID # 19US041759

Brief description of incident circumstances

Suspected Adverse Event: On 16 Jul 2019, the pet owner reported the following event for Ruby, a 13 year old (1 Feb 2006), 14.6 pound, neutered male Domestic Shorthair.
Unknown date, Jan 2017*: The cat began receiving FRONTLINE PLUS CATS (unsubstantiated) (lot unknown,package unavailable) monthly with unknown purchase history. The product application details are unknown. Fleas were seen prior to product application.
22 Jun 2019: The most recent date of application. Fleas were seen prior to product application. The cat is strictly indoors.
14 Jul 2019: The cat passed away at home. The cat had not presented to the veterinary clinic since 2017.
The cat has a pertinent medical history of hypothyroidism. The pet owner claims to have purchased all the Frontline through the veterinarian, but the clinic has no record. No further medical information expected.
UPDATE 19 Jul 2019: Clinic records show last purchase FRONTLINE PLUS CATS was 21 Aug 2014.

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: 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: 22 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: 14.6 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 #

19US041759

Version : 30-Jul-2019 at 15:35

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 Annette Unknown	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US044088
	Address Phoenix AZ U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 07-17-2019	Date registrant became aware of incident. 07-25-2019	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? 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)).	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 : 7-Aug-2019 at 21:55

Internal ID # 19US044088

Brief description of incident circumstances

Suspected Adverse Event: On 25 Jul 2019, a pet owner reported the following event for Botchi, an 11 year old, 115 pound, male Large Crossbred canine.
Unknown Date: The dog began receiving monthly applications of FRONTLINE PLUS DOG 89-132 LBS (Lot Unknown, Package Unavailable) topically between the shoulder blades in one spot.
1 Jul 2019*: The dog received 1 application of FRONTLINE.
14 Jul 2019: The dog presented to the groomer.
17 Jul 2019: The pet owner went on vacation and took Botchi with her. He started breathing strangely and continued to have difficulty breathing.
22 Jul 2019: The dog presented to the clinic and they discovered that the dog had cancer. The pet owner stated that the dog had a lot of tumors but it is unknown what diagnostics, if any, were performed. The pet owner stated that the dog died but it is unknown if the dog died on its own or was euthanized. No further medical information 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: 16 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Dyspnoea Neoplasia 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: 115 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 #
19US044088

* approximate

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US044534
	Address Ex. 6 PP – personal address WALTERBORO SC 29488 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 07-22-2019	Date registrant became aware of incident. 07-29-2019	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)).	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 : 9-Aug-2019 at 19:33

Internal ID # 19US044534

Brief description of incident circumstances

Suspected Adverse Event: On 29 Jul 2019, a pet owner reported the following event for Jaba, a 1 year old, 6 pound, intact male Chihuahua.
25 Jun 2019: The dog received 1 application of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) topically between the shoulder blades for the first time.
22 Jul 2019: The pet owner noticed the animal was not eating and drinking. The owner tried to tube feed the animal, the specifics are not clear if she placed it or the veterinarian placed it when she arrived at the clinic. The owner went to the veterinary clinic, it is unknown if any treatments were given or diagnostics were ran.
26 Jul 209: The animal passed. The owner went to the veterinary clinic, cause of death is unknown as owner did not wish to discuss event any further. The dog does have a prior case reported for fleas, see 19US038717. 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: 1 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: 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 Anorexia Adipsia 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: 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 #

19US044534

Version : 9-Aug-2019 at 19:33

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US045808
	Address Ex. 6 PP – personal address WYTHEVILLE VA 24382 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		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. 07-24-2019	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)).	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 : 5-Aug-2019 at 16:20

Internal ID # 19US045808

Brief description of incident circumstances

Suspected Adverse Event Claim: On 24 Jul 2019, the pet owner reported the following event for a 20 year old male cat of further unknown signalment.
1 Jan 2019*: The patient got their monthly dose of FRONTLINE PLUS CAT (lot unknown, reported refused inquiry). The cat was also on Royal Canin Urinary Diet at this time due to urinary problems, start of this is unknown.
2 Jan 2019*: The cat passed away, causes are unknown.
Further information is unknown as owner refused further inquiry.
There a total of 3 other felines in the household, who each had a case reported at this time. See cases 19US043714 and 19US045802. The owner's main purpose for the call was to discuss his flea issue in this forementioned cases. No further medical information expected.

Demographic information: Age: 20 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 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: 30 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 #
19US045808

* approximate

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 Lucille Unkown	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US046319
	Address PULLMAN WA 99163 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 07-24-2019	Date registrant became aware of incident. 08-05-2019	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 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)).	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 : 16-Aug-2019 at 15:22

Internal ID # 19US046319

Brief description of incident circumstances

Suspected Adverse Event: On 5 Aug 2019, the owner reported the following event for a 17 pounds, canine (all other signalments unknown).
15 July 2019*: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown, reporter not queried) was applied between the shoulder blades, by the pet owner.
24 July 2019*: The dog passed away from zinc poisoning. The owner did not give any other detailed information.
The owner stated that product did not work, but did not state in what form it was not working.
No further medical information is expected.
UPDATE 16 Aug 2019: The reportability was changed to 15-day

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: 9 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: Patient weight: 17 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 #

19US046319

* approximate

Version : 16-Aug-2019 at 15:22

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US046765
	Address Daytona Beach FL U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 01-01-2018	Date registrant became aware of incident. 08-06-2019	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? 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 : 16-Aug-2019 at 16:09

Internal ID # 19US046765

Brief description of incident circumstances

Suspected Adverse Event: On 06 Aug 2019, the animal owner reported the following event for an unknown 16.0 year old*, otherwise unknown signalment canine.
Unknown dates: The canine received FRONTLINE PLUS DOG (unsubstantiated) (lot and expiration unknown) (reporter refused) unknown dose via an unknown route at an unknown interval for an unknown length of time. It is unknown if the canine was experiencing any clinical signs.
Jan 2018*: The presented to the veterinary clinic. It is unknown if any diagnostics were performed. The canine was humanely euthanized due to undefined neoplasia. The remains have been disposed.
This is the extent of information known as the caller refused to report. Caller did not feel the pet's condition was related to the FRONTLINE PLUS. 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: 16 Year(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: 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 Neoplasia NOS		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 #

19US046765

* approximate

Version : 16-Aug-2019 at 16:09

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US046774
	Address Ex. 6 PP – personal address OAKLAND GARDENS NY 11364 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 12-31-2013	Date registrant became aware of incident. 08-06-2019	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? 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 : 19-Aug-2019 at 18:20

Internal ID # 19US046774

Brief description of incident circumstances

Suspected Adverse Event: On 06 Aug 2019, the animal owner reported the following event for a Poodle of otherwise unknown signalment.
Unknown dates: The canine received FRONTLINE PLUS DOG (unsubstantiated) (lot and expiration unknown) (reporter refused) unknown dose via an unknown route at an unknown interval for an unknown length of time. It is unknown if the canine was experiencing any clinical signs.
2013*: The canine expired due to age related conditions. It is unknown if it was a natural passing versus euthanasia.
This is the extent of information known as the caller refused to report. Caller did not feel the pet's condition was related to the FRONTLINE PLUS. 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: 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 #

19US046774

* approximate

Version : 19-Aug-2019 at 18:20

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 Carolynn Unknown	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US047664
	Address Unknown Washington D.C. DC U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		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. 08-09-2019	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? 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)).	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 : 23-Aug-2019 at 02:30

Internal ID # 19US047664

Brief description of incident circumstances

Suspected Adverse Event: On 9 Aug 2019, the pet owner reported the following event for Wiley, an unknown age, 90 pound, neutered male, Eskimo.
Unknown date: The patient received a dose of FRONTLINE PLUS DOG (F84101AP, invalid lot) (product unsubstantiated) and a dose of Interceptor. The animal was also on a daily unknown anxiety medication, as well as a daily dose of an unknown heart medication for heart issues, owner stated murmur but is unsure.
Unknown date: The patient began experiencing liver failure and became anemic, this was diagnosed at the clinic. It is unknown if any treatments were given for this.
Unknown date: The animal passed away.
It is unknown how long he had been on FRONTLINE prior to this, as owner cannot remember. Owner primary concern for call was to see if FRONTLINE had an expiration date. 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 Hepatic failure Anaemia NOS		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: 90 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 #

19US047664

* approximate

Version : 23-Aug-2019 at 02:30

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US047892
	Address Unknown CA U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-02-2018	Date registrant became aware of incident. 08-09-2019	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)).	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 : 23-Aug-2019 at 17:34

Internal ID # 19US047892

Brief description of incident circumstances

Suspected Adverse Event: On 9 Aug 2019, the pet owner reported the following event for Buddy, a Saint Bernard mix of further unknown signalment.
Unknown dates: Unknown FRONTLINE PLUS (lot unknown) (product unsubstantiated) was applied topically by the reporter in an unknown location on the dog. It's unknown if the canine has previously received this product. An unknown duration following product application, the canine was diagnosed with metastatic anal sac carcinoma. It's unknown if any treatment was pursued before Buddy was subsequently humanely euthanized an unknown time following diagnosis.
The reporter was only calling to inquire about FRONTLINE PLUS and was not interested in providing additional information about Buddy's event. Because the reporter did not want to report the case in detail, the product lot number could not be obtained. Three additional reports were created. Please see cases 19US047835, 19US047889, and 19US047895. 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: 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 Metastatic neoplasia 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 #

19US047892

* approximate

Version : 23-Aug-2019 at 17:34

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US047895
	Address Unknown CA U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-02-2018	Date registrant became aware of incident. 08-09-2019	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)).	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 : 21-Aug-2019 at 23:26

Internal ID # 19US047895

Brief description of incident circumstances

Suspected Adverse Event: On 9 Aug 2019, the pet owner reported the following event for Tank, a male canine of further unknown signalment.
Unknown dates: Unknown FRONTLINE PLUS (lot unknown) (product unsubstantiated) was applied topically by the reporter in an unknown location on the dog. It's unknown if the canine has previously received this product. An unknown duration following product application, the canine was diagnosed with metastatic anal sac carcinoma. An unknown duration post diagnosis, Tank stopped eating his food entirely and began starving despite otherwise acting completely normal. It's unknown if any treatment was pursued before Tank was humanely euthanized on an unknown date in Oct 2018, an unknown duration following diagnosis.
The reporter was only calling to inquire about FRONTLINE PLUS and was not interested in providing additional information about Tank's event. Because the reporter did not want to report the case in detail, the product lot number could not be obtained. Three additional reports were created. Please see cases 19US047835, 19US047889, and 19US047892. 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: 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 Anal sac disorder Anorexia 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			

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

Internal ID #

19US047895

* approximate

Version : 21-Aug-2019 at 23:26

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US048117
	Address Ex. 6 PP – personal address SAN CLEMENTE CA 92672 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-01-2019	Date registrant became aware of incident. 08-12-2019	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? 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 : 24-Aug-2019 at 18:59

Internal ID # 19US048117

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 12 Aug 2019, animal owner reported the following event for Leah, a 15 year old, 84 pound, female neutered Golden Retriever.
28 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (Lot unknown) topically for the first time.
27 Jul 2019: A dose was applied.
01 Aug 2019: The pet owner saw several fleas and applied another dose.
05 Aug 2019: The pet owner elected to euthanize the dog for chronic arthritis and the inability to walk.
The dog had chronic arthritis issues and difficulty walking for several months. The dog was indoors except to urinate and defecate. The owner would assist the dog in walking. There are no other pets in the home. 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: 15 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 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 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: 84 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 #

19US048117

Version : 24-Aug-2019 at 18:59

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US048247
	Address Ex. 6 PP – personal address SODUS NY 14551 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 07-09-2019	Date registrant became aware of incident. 08-09-2019	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)).	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 : 8-Oct-2019 at 16:11

Internal ID # 19US048247

Brief description of incident circumstances

Suspect Adverse Event and Lack of Efficacy: On 09 Aug 2019, the pet owner reported the following event for 1 feline of further unknown signalment.
07 Jun 2019 and 07 Jul 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (R41105AW) topically between the shoulder blades of 5 cats.
09 Jul 2019*: The owner saw 12 fleas on the cat. The owner combed the cat.
10 Jul 2019*: The cat died.
Please reference case 19US047646 for flea incident. No further medical information expected.
Update 29 Aug 2019: Upon internal review it was determined that an LOE in only four of the cats was reported in Case 19US047646 thus a Product Problem Type of LOE was added to this case to account for the LOE event in this patient.

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: 2 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 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: 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 #

19US048247

Version : 8-Oct-2019 at 16:11

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US048673
	Address Ex. 6 PP – personal address RICHMOND OH 43944 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-27-2017	Date registrant became aware of incident. 08-14-2019	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)).	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 : 27-Aug-2019 at 20:52

Internal ID # 19US048673

Brief description of incident circumstances

Suspected Adverse Event: On 14 Aug 2019 a pet owner reported the following event for Higgins, a 7.5 pound, 19 year old, neutered male Domestic Shorthair.
18 Jul 2019: Owner applied FRONTLINE PLUS CATS (S40210CW) to the skin on the animal's neck.
26 Jul 2019: Cat was being watching by a house sitter while owner was out of town and she told owner that this day Higgins was acting normally in the morning. An unknown amount of hours later the cat was lateral on the floor convulsing and having trouble breathing and this continued until he died approximately 1 to 2 hours later at home. No further details about the event are known by the owner. No treatment was provided and the cat was not taken to a clinic. The cat has received FRONTLINE PLUS for an unknown amount of years without issue. Higgins had been eating more, losing weight, and having soft stools for the last 2 to 3 years of his life, and had lost 5.5 pounds during this time. He was not on any regular medications. he other cat in the household who died after receiving FRONTLINE from the same lot number has his own case: 19US048676. 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: 19 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: 5 Week(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Increased appetite Weight loss Diarrhoea 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: 24 Month(s) 1 Week(s) Patient weight: 7.5 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 #

19US048673

* approximate

Version : 27-Aug-2019 at 20:52

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US048676
	Address Ex. 6 PP – personal address RICHMOND OH 43944 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-08-2019	Date registrant became aware of incident. 08-14-2019	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)).	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 : 28-Aug-2019 at 21:06

Internal ID # 19US048676

Brief description of incident circumstances

Suspected Adverse Event: On 14 Aug 2019 a pet owner reported the following event for Rusty, a 13 pound, 10 year old, neutered male Domestic Shorthair.
1 Aug 2019: Owner applied FRONTLINE PLUS CATS (S40210CW) to the skin on the animal's neck.
8 Aug 2019: Owner left the home around 12:00 pm and cat was acting normally. At 4:20 pm the husband came home and found Rusty was dead. His tongue was out, so owner believes he convulsed before death because the other cat she reported that died had his tongue out. There is no other evidence that the cat convulsed. Rusty had seasonal allergies which worsened when he went outside and owner described as breathing difficulties, but could not elaborate on. He was in good health and took no regular medications. The cat had been receiving FRONTLINE PLUS monthly for an unknown number of years without issue. The other cat in the household who died after receiving FRONTLINE from the same lot number has his own case: 19US048673. 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: 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 Week(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: 13 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 #

19US048676

* approximate

Version : 28-Aug-2019 at 21:06

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US048681
	Address U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-12-2019	Date registrant became aware of incident. 08-14-2019	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)).	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 : 23-Sep-2019 at 15:51

Internal ID # 19US048681

Brief description of incident circumstances

Suspected Adverse Event: On 14 Aug 2019, the owner reported the following event for Tommy, a 11 pound, 17.5 year old*, neutered male Domestic Shorthair.
3 Aug 2019*: The owner applied 1 dose of FRONTLINE PLUS CATS (Lot Unknown, Package Unavailable) topically, in between the shoulder blades.
12 Aug 2019*: The owner heard Tommy vocalize loudly. When she cam in the room, he was limp on the floor, wheezing, eyes partly shut, and all legs out stretched in one direction. She went to put him in his carrier and Tommy became quiet. The owner believed he passed on the ride to clinic.
Tommy did have an unknown urinary and bowel issues as well as a history of polyuria. His exact medical history is unknown as he has not been to a vet since 2012*. The owner also was trying other unknown flea/tick products at unknown administrations dates. No further information at this time.
UPDATE 23 SEP 2019: corrected the company assessment to serious.

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: 17.5 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: 9 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Hypotonia Bronchitis Vocalisation Blepharospasm Muscle stiffness 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: 11 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 #

19US048681

* approximate

Version : 23-Sep-2019 at 15:51

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 Michele Unknown	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US049891
	Address U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 04-12-2019	Date registrant became aware of incident. 08-20-2019	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 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? 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)).	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 : 27-Aug-2019 at 23:43

Internal ID # 19US049891

Brief description of incident circumstances

Suspected Adverse Event: On 20 Aug 2019, animal owner reported the following event for a unknown signalment dog.
11 Apr 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (Lot unknown) topically.
12 Apr 2019: The dog was euthanized for a liver mass.
All additional information not obtained as the owner declined 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: 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)	List signs/symptoms/adverse effects Hepatic neoplasm 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 #

19US049891

Version : 27-Aug-2019 at 23:43

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US050810
	Address Ex. 6 PP – personal address HOUTZDALE PA 16651 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 01-01-2011	Date registrant became aware of incident. 08-23-2019	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? 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 : 30-Aug-2019 at 14:35

Internal ID # 19US050810

Brief description of incident circumstances

Suspected Adverse Event: On 23 Aug 2019, while reporting cases 19US048837, 19US050839, 19US050840, and 19US050841, the animal owner reported the following event in Luke, a 9 year old, male neutered, Miniature Poodle.
2011*: The canine was administered FRONTLINE PLUS DOGS 5-22 LBS (lot, expiration unknown. Package unavailable). An unknown amount of time later, the canine died due to kidney disease. The canine had been receiving monthly doses of FRONTLINE PLUS since he was a puppy with no history of reactions.
Caller non receptive. No further information provided nor 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: 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 Renal 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: 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 #

19US050810

* approximate

Version : 30-Aug-2019 at 14:35

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US051903
	Address Ex. 6 PP – personal address WATSONVILLE CA 95076 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-27-2019	Date registrant became aware of incident. 08-29-2019	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)).	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 : 11-Sep-2019 at 15:10

Internal ID # 19US051903

Brief description of incident circumstances

Suspected Adverse Event: On 29 Aug 2019, the owner reported the following event for a 12 years old, female, feline (all other signalments unknown.
26 Aug 2019: One vial of FRONTLINE PLUS CATS (R41105AW) was applied between the shoulder blades, by the pet owner.
27 Aug 2019: The cat was lethargic. The cat stop eating and drinking. The cat also had a difficult time urinating.
28 Aug 2019: The cat could not move. The cat present to the SPCA and the Vet on staff stated that the cat was brain dead. The cat was euthanized.
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: 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: 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 Adipsia Dysuria Akinesia 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: 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 #

19US051903

Version : 11-Sep-2019 at 15:10

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US052203
	Address Ex. 6 PP – personal address GREENSBURG PA 15601 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 06-15-2019	Date registrant became aware of incident. 08-30-2019	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? 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 : 12-Sep-2019 at 17:55

Internal ID # 19US052203

Brief description of incident circumstances

Suspected Adverse Reaction and Lack of Efficacy Claim: On 30 Aug 2019 a pet owner reported the following event for a 9 year old, spayed female Domestic Shorthair of unknown weight.
2 Jun 2019:Owner applied FRONTLINE PLUS CATS (S40815AW) to the skin on the animal's neck.
Unknown Date Jun 2019*: Cat started scratching and owner seeing a large amount of flea dirt in her bed where the cat sleeps.
9 Jul 2019: Cat presented to the clinic for unknown symptoms that started on an unknown date and was diagnosed with lung cancer and subsequently euthanized this day.
The cat did go outside with owner, but stayed mostly on the porch. There are woods at the perimeter of the property with wildlife, but the owner says the cat did not go there.
It is unknown if the owner applied FRONTLINE prior to 2 Jun 2019. There was one other cat in the home who also had FRONTLINE PLUS applied and has her own case: 19US052178.
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 : 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: 13 Day(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 Pruritus Pulmonary neoplasm 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 #

19US052203

* approximate

Version : 12-Sep-2019 at 17:55

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US053365
	Address U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-20-2019	Date registrant became aware of incident. 09-06-2019	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? 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 : 19-Sep-2019 at 16:20

Internal ID # 19US053365

Brief description of incident circumstances

Suspected Adverse Event and Lack of Efficacy Claim: On 6 Sep 2019, the owner reported the following event for a feline with unknown signalment.
Jul 2019*: The owner noticed that the cat was scratching more than usual.
19 Jul 2019: The owner started on FRONTLINE PLUS CATS (S40606AW), topically on the neck.
19 Aug 2019: The most recent dose was applied.
20 Aug 2019: The owner reported that the cat was still scratching after the second dose.
25 Aug 2019: The owner found the pet motionless on the ground. She was presented to the clinic where it was pronounced dead.
The cat is considered strictly indoor. The cat did not have any known medical issues or conditions. There were no fleas seen prior to product use. There was a dog in the home that was also on FRONTLINE FOR DOG 5-22 (S61006AL)) that also was itching and had fleas (Please see case 19US053352). The owner has been treating monthly with FRONTLINE since Jul 2019*. 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: 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: 4 Week(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: 31 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 #

19US053365

Version : 19-Sep-2019 at 16:20

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 Candy Unknown	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US053527
	Address U.S.A		Address --UNKNOWN--	
	Phone #	Ex. 6 PP – personal phone	Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-15-2017	Date registrant became aware of incident. 09-06-2019	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? 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 : 19-Sep-2019 at 20:15

Internal ID # 19US053527

Brief description of incident circumstances

Suspected Adverse Event: On 06 Sep 2019, animal owner reported the following event for an unknown signalment Basset hound.
*01 Aug 2017: A dose of FRONTLINE PLUS DOG 23-44 LBS (lot unknown/ package unavailable) topically.
*15 Sep 2017: The dog passed away for unknown reasons.
The owner declined reporting case details. 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: 6 Week(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 #

19US053527

* approximate

Version : 19-Sep-2019 at 20:15

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 Helen unknown	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US053605
	Address unknown U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 06-01-2018	Date registrant became aware of incident. 09-09-2019	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? 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 : 19-Sep-2019 at 17:25

Internal ID # 19US053605

Brief description of incident circumstances

Suspected Adverse Event: On 9 Sept 2019, the pet owner reported the following event for a canine of unknown signalment.
Unknown date: The dog was given a dose of FRONTLINE PLUS (unsubstantiated) (lot and expiration unknown, not queried).
2018*: The dog passed away of unknown causes.
No further medical information expected.

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 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 #

19US053605

* approximate

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US053645
	Address unknown U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 02-01-2019	Date registrant became aware of incident. 09-09-2019	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)).	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 : 19-Sep-2019 at 17:33

Internal ID # 19US053645

Brief description of incident circumstances

Suspected Adverse Event: On 9 Sep 2019, a pet owner reported the following event for a canine of unknown signalment.
Unknown Date: The dog began receiving FRONTLINE PLUS DOG 45-88 LBS (Lot and Expiration Unknown, Package Unavailable) in an unknown manner.
Unknown Date: The dog was euthanized due to cancer.
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: 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: 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 #

19US053645

* approximate

Version : 19-Sep-2019 at 17:33

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter) Dr UNKNOWN	Internal ID # 19US053675
	Address Ex. 6 PP – personal address SANGER TX 76266 U.S.A		Address PAWS AND CLAWS VETERINARY CLINIC 302 S ACKER ST SANGER TX, 76266 U.S.A	
	Phone # Ex. 6 PP – personal phone		Phone # 940-458-2529	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-02-2019	Date registrant became aware of incident. 09-09-2019	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)).	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 # 19US053675

Brief description of incident circumstances

Suspected Adverse Event: On 9 Sep 2019, the pet owner reported the following event for Sadie, an 8 year old*, 6 pound*, intact female, Chihuahua.
2 Sep 2019: The reporter applied one vial of FRONTLINE PLUS DOG 5-22 LBS (FL+) (S61412) topically between Sadie's shoulder blades. It's unknown if she's previously received FL+ or if any other products were given within 31 days prior to FL+ administration.
4 Sep 2019: Approximately 36 hours following FL+ application, the canine became lethargic, emetic, ataxic, and experienced onset diarrhea. The reporter confirmed she did not get into anything including rodenticides and/or insecticides.
Unknown dates: Sadie experienced an unknown number of seizures. The reporter cannot confirm how long each one lasted, but states the longest one lasted for a couple of minutes. During a couple of the seizures, Sadie was responsive and the reporter was able to calm her down via unknown methods; however, during other seizures, she was not responsive and was seen paddling by the pet owner. He also reported that during one of the seizures, Sadie was acting aggressive and showing her teeth and during a different seizure, she just started barking for an unknown duration which the reporter implied said behavior to be uncharacteristic of her. He did not confirm whether the canine was responsive during either of those seizures. For all of the seizures experienced, Sadie never urinated or defecated and it couldn't be confirmed how long before she recovered after each one. She also has no prior history of similar neurologic symptoms.
6 Sep 2019: Due to the ongoing symptoms, Sadie presented to a general practitioner where it was determined her blood glucose (BG) was very low. The value could not be confirmed by the reporter. Due to Sadie's condition, she was immediately referred to a emergency clinic where she presented an unknown time later that day. She was subsequently hospitalized overnight at the emergency clinic where unknown blood work
performed was respectively negative or WNL. Supportive care consisted of unknown IV fluids.
7 Sep 2019: The canine was discharged. Her condition at that time is unknown.
8 Sep 2019: Sadie passed away at home.
The reporter states Sadie was in great health at the time of FL+ application and strongly believes the FL+ to be responsible for Sadie's demise. No further medical information expected.
UPDATE 9 Sep 2019: Per conversation with attending veterinarian, product not purchased from clinic and patient had never been seen prior to visit 3 Sep 2019; owner applied FL on 31 Aug 2019 and washed pet 3 days later; on 3 Sep 2019 patient presented to attending clinic and had been seizuring for some time; blood glucose was 21 and oral glucose was administered which brought value up to 140; patient was referred to ER and not seen again by attending. No further medical information is expected.
UPDATE 11 Sep 2019: Per conversation with emergency clinic staff member, patient was admitted on 3 Sep 2019 and discharged on 4 Sep 2019; owner declined all treatment other than IV fluids. No further medical information is expected.
UPDATE 13 Sep 2019: Per medical record received 13 Sep 2019, emergency clinic veterinarian suspected insulinoma as the cause for patient's persistent hypoglycemia and subsequent seizure activity. 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: 8 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 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) IV fluids, oral and IV	List signs/symptoms/adverse effects Lethargy Emesis Ataxia Diarrhoea Convulsion Aggression Vocalisation Hypoglycaemia 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: 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 #

19US053675

* 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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US053942
	Address Ex. 6 PP – personal address CLAYMONT DE 19703 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 04-01-2019	Date registrant became aware of incident. 09-09-2019	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? 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 : 20-Sep-2019 at 22:41

Internal ID # 19US053942

Brief description of incident circumstances

Suspected Adverse Event: On 09 Sep 2019, the animal owner reported the following event for Lexi, a 14 year old*, 100 pound*, spayed female Labrador Retriever Chesapeake Bay Retriever Mix.
Jul 2018* though 13 Jul 2019*: She received FRONTLINE PLUS DOG 45-88 LBS (lot unknown) (package unavailable) one dose applied topically between the shoulders.
Apr 2019*: She had undefined clinical signs. She presented to a veterinary clinic on an unknown date. She was diagnosed with undefined neoplasia.
07 Sep 2019: She was humanely euthanized for quality of life related to neoplasia.
She previously received FRONTLINE PLUS monthly seasonally for an unknown length of time with no previous adverse effects noted. There are two felines in the house that were reported for lack of efficacy claim (see case 19US053943). This is the extent of information known as caller declined to complete reporting. 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: 14 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: 9 Month(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Systemic disorder NOS Neoplasia 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: 100.0 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 #

19US053942

* approximate

Version : 20-Sep-2019 at 22:41

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US045727
	Address Green Bay WI U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		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. 08-02-2019	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? 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 : 16-Aug-2019 at 15:51

Internal ID # 19US045727

Brief description of incident circumstances

Suspected Adverse Event: On 02 Aug 2019, the animal owner reported the following event for an unknown canine of unknown signalment.
Unknown dates: The canine received FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown) (reporter refused) unknown volume, via an unknown route, at an unknown location of the body, at unknown intervals for an unknown length of time. It is unknown if the canine experienced any clinical signs. It is unknown if any diagnostics or treatments were provided. The canine was humanely euthanized due to undefined cardiac issues on an unknown date. The remains have been disposed.
The caller did not feel that the FRONTLINE PLUS was related to the canines cardiac issues and refused to report. 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: 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 Cardiac disorder NOS		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 #

19US045727

* approximate

Version : 16-Aug-2019 at 15:51

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US054803
	Address Ex. 6 PP – personal address POMPANO BEACH FL 33064 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 12-31-2018	Date registrant became aware of incident. 09-11-2019	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? 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 : 25-Sep-2019 at 16:04

Internal ID # 19US054803

Brief description of incident circumstances

Suspected Adverse Event: On 11 Sep 2019, the pet owner reported the following event for a 19 year old* dog with otherwise unknown signalment. The caller was calling for an event for another household dog (Bowser) and mentioned that he was using left over product that was for a dog that has passed.
Unknown date, approx Dec 2000* for reporting: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (M63408AL) monthly.
Unknown date (approx. 31 Dec 2018* for reporting purposes): The dog passed away of unknown causes. See related LOE case 19US054394. No other information could be provided. No more information expected.

Demographic information: Age: 19 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: 30 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 #
19US054803

* approximate

Version : 25-Sep-2019 at 16:04

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter) Dr UNKNOWN	Internal ID # 19US055066
	Address U.S.A		Address KNOX VETERINARY CLINIC 2235 S US HIGHWAY 35 KNOX, IN 46534 U.S.A	
	Phone # Ex. 6 PP – personal phone		Phone # 574-772-5554	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-13-2019	Date registrant became aware of incident. 09-16-2019	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)).	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 : 24-Sep-2019 at 20:25

Internal ID # 19US055066

Brief description of incident circumstances

Suspected Adverse Event: On 16 Sep 2019, the owner reported the following event for Bobbit, a 12 month old (born approx. 1 Sep 2018), approx. 5 pound, spayed female, feline unknown.
11 Sep 2019: First dose of FRONTLINE PLUS CATS (S40606AW) was applied topically between the shoulder blades, by the owner. The cat had fleas for approx. 1 week before the first dose was applied.
13 Sep 2019: The cat started laying around and, wasn't moving, and was meowing more than normal.
Unknown date: The owner tried bathing the cat and giving it Gatorade.
16 Sep 2019: The cat died.
The cat was not seen by a veterinarian. No further medical information expected.

Demographic information: Age: 12 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: 2 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lying down 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: 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 #
19US055066

* approximate

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US055198
	Address Ex. 6 PP – personal address BLOOMINGDALE OH 43910 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-03-2019	Date registrant became aware of incident. 09-16-2019	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? 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)).	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 : 18-Oct-2019 at 21:46

Internal ID # 19US055198

Brief description of incident circumstances

Suspected Adverse Event: On 16 Sep 2019 a pet owner reported the following event for 29 cats of unknown signalment, and 1 cat named Molli, a 28 pound male of unknown other signalment.
3 Sep 2019: Owner applied FRONTLINE SPRAY (S02207A), 1 pump per pound , to 44 cats and 29 of those cats died within 3 to 48 hours. Owner applied 5 pumps to Molli and he died in 48 hours. The owner has been applying the product to the cats seasonally for an unknown number of years, starting in Jun 2019* this season. The application on 3 Sep 2019 was the first time she used this bottle. The owner reported the cats showed no signs of illness before death and that she just found them dead over two days after application. No further medical information expected.
UPDATE 14 Oct 2019: Per pet owner,
Called owner to request a picture of the product. She stated she has thrown the product away. She stated that upon talking to her veterinarian, he told he believed the cats had a virus since she has such a large population of cats in the home and a large amount of animals died at once. 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: 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: 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 #
19US055198

Version : 18-Oct-2019 at 21:46

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US055396
	Address unknown U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 01-30-2018	Date registrant became aware of incident. 09-17-2019	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)).	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 : 27-Sep-2019 at 18:43

Internal ID # 19US055396

Brief description of incident circumstances

Suspected Adverse Event: On 17 Sep 2019, the pet owner reported the following event for a feline of unknown signalment.
1 Jan 2018*: The cat received 1 dose of FRONTLINE PLUS CATS (lot and expiration unknown, package unavailable) applied topically by the animal owner.
30 Jan 2018*: The cat passed away due to unknown causes.
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: 29 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 #

19US055396

* approximate

Version : 27-Sep-2019 at 18:43

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US055572
	Address MILWAUKEE WI 53204 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-02-2019	Date registrant became aware of incident. 09-17-2019	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? 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 : 22-Oct-2019 at 16:09

Internal ID # 19US055572

Brief description of incident circumstances

Suspected Lack of Efficacy Claim and Adverse Event: 17 Sep 2019: An owner reported the following event in 1 ferret of unknown further signalment.
01 Sep 2019*: The owner administered one FRONTLINE PLUS CATS (lot unknown, package unavailable)(product unsubstantiated*) in an off label manner, topically in an unknown area. An unknown amount of fleas were seen at the time of application. It is unknown if this was the first time, seasonal, or yearly application.
02 Sep 2019*: The owner is still seeing an unknown amount of fleas.
03 Sep 2019*: The ferret died of unknown causes.
The ferret was in an unknown environment. There are 5 dogs (19US055574)(19US055575), 5 cats (19US055576), 2 rabbits (19US055541), and 1 hamster in the home. Dates approximate for reporting purposes. 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: 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 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: 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 #

19US055572

* approximate

Version : 22-Oct-2019 at 16:09

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US055824
	Address U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 12-01-2015	Date registrant became aware of incident. 09-18-2019	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)).	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 : 1-Oct-2019 at 22:30

Internal ID # 19US055824

Brief description of incident circumstances

Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 18 Sep 2019, while inquiring about pricing of FRONTLINE PLUS, an animal owner reported the following event in a Greyhound. All other signalment unknown.
01 Jan 2015*: The canine was administered FRONTLINE PLUS DOGS 45-88 LB (lot expiration unknown. Product unavailable) for the first time. Canine had fleas at time of administration. Canine received product monthly.
01 Nov 2015*: The canine was administered FRONTLINE PLUS.
01 Dec 2015*: Canine still has fleas. Canine died due to lymphoma. No necropsy done.
The canine was administered FRONTLINE PLUS every month on an unknown date. The canine had ongoing flea problems. The animal owner stated that she puts salt at the perimeter of every room to help kill fleas. It is unknown if there were housemates. It is unknown if canine had access outdoors.
Intent of call was not to report. Due to lack of case information, all dates are approximate.
No further information provided.

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: 11 Month(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Lymphoma Death 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: 10 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 #
19US055824

* approximate

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 Unknown Lewis	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US055923
	Address U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-01-2019	Date registrant became aware of incident. 09-18-2019	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? 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 : 1-Oct-2019 at 18:06

Internal ID # 19US055923

Brief description of incident circumstances

Suspected Adverse Event: One 18 Sep 2019, the pet owner called to report the following event canine of unknown singlement.
Sep 2019*: It is unknown how long the canine received FRONTLINE PLUS DOG 23-44 LBS (lot unknown)(reporter not queried). The canine passed away on an unknown date.
The canine has an unknown medical and drug reaction history. Reporter declined to give additional information. Reported stated that pet passed away from old age. No additional 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: 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: 19 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: Unknown per Unknown Expose duration: Patient weight: 40 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 #

19US055923

* approximate

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US056069
	Address Ex. 6 PP – personal address GLOVERSVILLE NY 12078 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 01-01-2016	Date registrant became aware of incident. 09-19-2019	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)).	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 : 2-Oct-2019 at 20:54

Internal ID # 19US056069

Brief description of incident circumstances

Suspected Adverse Event: On 19 Sept 2019, the pet owner reported the following event for a feline of unknown signalment.
2016*: The cat was given a dose of FRONTLINE PLUS CATS (lot unknown, package unavailable). Following on an unknown date, the cat starting vomiting blood and passed away.
It is unknown how long the cat was on FRONTLINE. Case was reported with case 19US056063. 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: 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 Haematemesis Bee systemic disorder NOS		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 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 #

19US056069

* approximate

Version : 2-Oct-2019 at 20:54

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 Paul UNKNOWN	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US056258
	Address U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-15-2019	Date registrant became aware of incident. 09-20-2019	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 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? 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 : 30-Sep-2019 at 19:59

Internal ID # 19US056258

Brief description of incident circumstances

Suspected Adverse Event: On 20 Sep 2019 a pet owner reported the following event for a 5 to 22 pound caine of unknown other signalment.
Unknown date: Dog started receiving FRONTLINE PLUS DOG 5-22 LBS (lot unknown, Package unavailable).
Unknown date: Dog died of unknown causes.
No further details were obtained as the owner did not intend to report, but was asking about using the leftover product on his larger dog. 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: 2 Week(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: 5 - 22 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 #

19US056258

* approximate

Version : 30-Sep-2019 at 19:59

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US056615
	Address Ex. 6 PP – personal address GALESVILLE WI 54630 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-03-2019	Date registrant became aware of incident. 09-23-2019	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)).	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 : 30-Sep-2019 at 16:20

Internal ID # 19US056615

Brief description of incident circumstances

Suspected Adverse Event: On 23 Sep 2019, the pet owner reported the following event for a feline, 2 pound*, 4 month old*, intact. All other signalment is unknown.
1 Sep 2019*: One vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) was applied. It is unknown how the product was applied.
3 Sep 2019*: The cat was jittery and having convulsions. The cat did not present to the clinic and no treatment was provided.
4 Sep 2019*: The cat passed.
There are 28 other cats in the household that received the product with no symptoms. There is one other cat that also experienced symptoms (see case 19US056637). The owner also reported a quality issue with the product (see case 19US056646) No further medical information expected.
UPDATE 30 Sep 2019: Added local assessments.

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: 4 Month(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: 2 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)	List signs/symptoms/adverse effects Muscle tremor 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: Patient weight: 2.000 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 #

19US056615

* approximate

Version : 30-Sep-2019 at 16:20

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US056637
	Address Ex. 6 PP – personal address GALESVILLE WI 54630 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-03-2019	Date registrant became aware of incident. 09-23-2019	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)).	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 : 30-Sep-2019 at 15:14

Internal ID # 19US056637

Brief description of incident circumstances

Suspected Adverse Event: On 23 Sep 2019, the pet owner reported the following event for a feline, 3.5 pound*, 6 month old*, spayed female. All other signalment is unknown.
1 Sep 2019*: One vial of FRONTLINE PLUS CATS (lot unknown, package unavailable) was applied. It is unknown how the product was applied.
3 Sep 2019*: The cat did not want to eat or drink. The cat did not present to the clinic and no treatment was provided.
4 Sep 2019*: The cat passed.
There are 28 other cats in the household that received the product with no symptoms. There is one other cat that also experienced symptoms (see case 19US056615). The owner also reported a quality issue with the product (see case 19US056646). 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: 6 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: 2 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 Adipsia 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: 3.5 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 #

19US056637

* approximate

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US057278
	Address U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-09-2019	Date registrant became aware of incident. 09-16-2019	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 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)).	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 : 4-Oct-2019 at 19:00

Internal ID # 19US057278

Brief description of incident circumstances

Suspected Adverse Event: On 16 Sep 2019, the pet owner reported the following event for a medium crossbred canine. All other signalments unknown, owner declined to complete report.
20 Aug 2019: 1 vial of FRONTLINE PLUS DOG 22-44 LBS(S60401AZ) was applied to the dog in one area between the shoulder blades.
9 Sep 2019: The dog passed aways from unknown causes The pet owne declined to discuss.
There is on other dog in the home see case 19US050152. No further information.
UPDATE 04Oct2019: On internal review, it was noted the Date First Received for this case was 16 Sep 2019. No further information.

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: 20 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 #
19US057278

Version : 4-Oct-2019 at 19:00

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 Susan UNKNOWN	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US057587
	Address U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-22-2019	Date registrant became aware of incident. 09-26-2019	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)).	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 : 2-Oct-2019 at 21:24

Internal ID # 19US057587

Brief description of incident circumstances

Suspected Adverse Event: On 26 Sep 2019 a pet owner reported the following event for a male dog of unknown signalment.
Unknown date: The dog started receiving FRONTLINE PLUS DOG 89-132 LBS (lot unknown, reporter not queried).
Unknown date: Dog died or was euthanized due to age related issues.
No further details are known. The pet owner was not calling to report this event, but to ask about using the product off label with her smaller dog. Confirmed with the pet owner that the dog's death was not related to the FRONTLINE. No further medical information expected.

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: 8 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: Unknown per Unknown Expose duration: 8 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 #
19US057587

* approximate

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US057658
	Address Ex. 6 PP – personal address MELBOURNE IA 50162 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		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. 09-25-2019	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? 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 : 9-Oct-2019 at 22:56

Internal ID # 19US057658

Brief description of incident circumstances

Suspected Adverse Event: On 25 Sep 2019, the pet owner reported the following event for Basset Hound of further unknown signalment.
2018*: The patient got their dose of FRONTLINE PLUS DOG (Unsubstantiated)(lot and expiration unknown, report refused). It is unknown where the dose was applied on the animal.
2018*: The animal was diagnosed with cancer, and passed away an unknown time after.
The owner refused further inquiry. The owner had originally reported a lack of efficacy for his current animals, see case 19US057333. 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: 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 Neoplasia 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: 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 #

19US057658

* approximate

Version : 9-Oct-2019 at 22:56

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US057752
	Address Ex. 6 PP – personal address GIRARD IL 62640 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		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. 09-27-2019	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)).	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 : 7-Oct-2019 at 21:43

Internal ID # 19US057752

Brief description of incident circumstances

Suspected Adverse Event: On 27 Sep 2019, the pet owner reported the following event for a 15 year old* canine of unknown signalment.
Unknown Date: The pet received FRONTLINE PLUS DOG 89-132 LBS (lot unknown) (reporter not queried), unknown volume via an unknown route, at an unknown location, monthly, seasonally for unknown length of time. It is unknown experienced any clinical signs. The pet expired on an unknown date.
The owner called to report a lack of efficacy case, see case 19US057720. This is the extent of information known. 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: 15 Year(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:	
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			

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

Internal ID #

19US057752

* approximate

Version : 7-Oct-2019 at 21:43

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 UNKNOWN	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US058092
	Address SAINT PAUL MN 55106 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-16-2019	Date registrant became aware of incident. 09-30-2019	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? 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 : 11-Oct-2019 at 21:22

Internal ID # 19US058092

Brief description of incident circumstances

Suspected Adverse Event: On 30 Sep 2019 a pet owner reported the following event for a 12 year old cat of unknown other signalment.
7 Sep 2019: Owner applied FRONTLINE PLUS CATS (lot unknown, Package unavailable) in an unknown location, for the first time in an unknown time frame.
Unknown date: The owner found the cat dead.
The owner declines to make a report or give further details. She states she does not think it was related to the product. She mentioned this cat while reporting a suspected lack of efficacy for her other 6 cats in case 19US058087. 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: 12 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: 9 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 #

19US058092

Version : 11-Oct-2019 at 21:22

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US058325
	Address EASLEY SC 29640 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 02-10-2019	Date registrant became aware of incident. 08-19-2019	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)).	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 : 1-Oct-2019 at 21:05

Internal ID # 19US058325

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 19 Aug 2019, the pet owner reported the following event for a canine of further unknown signalment.
UNKNOWN DATE: The pet owner found an unknown number of fleas on the dog.
09 Feb 2019, 09 Mar 2019, 09 Apr 2019, 09 May 2019, 09 Jun 2019, and 09 Jul 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S61902AL) topically between the shoulder blades.
10 Feb 2019* to 01 Aug 2019*: The owner sees fleas on the dog daily.
UNKNOWN DATE: The dog passed away from old age.
The owner has not been bit. There is another dog in the home reference case 19US049528. There is also an indoor only cat in the home, that is not having issues and is not being treated with any product. The owner has not seen fleas in the home and there is only hardwood in the home. The dogs are indoor and go outside for the bathroom. 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: 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 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: 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 #

19US058325

* approximate

Version : 1-Oct-2019 at 21:05

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US058394
	Address New City NY U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-11-2019	Date registrant became aware of incident. 09-27-2019	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)).	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 : 10-Oct-2019 at 23:22

Internal ID # 19US058394

Brief description of incident circumstances

Suspected Adverse Event: On 27 Sep 2019, the owner called and reported the following event of a feline of unknown signalment
Unknown date: The pet began receiving FRONTLINE PLUS CAT (Lot unknown) (reporter no queried). It is unknown how the owner is applying the product.
Unknown date: The pet passed away of unknown cause.
It is unknown if the pet was experiencing fleas. There are 8 other felines in the home and 2 canines. The environment is unknown. The other pets are experiencing fleas. See cases 19US057904, 19US058463, and 19US058456. Owner did no provide any more information. 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: 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 #

19US058394

* approximate

Version : 10-Oct-2019 at 23:22

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter) Dr Carole CHAPMAN	Internal ID # 19US038386
	Address Ex. 6 PP – personal address BOYNTON BEACH FL 33436 U.S.A		Address BEST FRIENDS VETERINARY HOSPITAL 4949 S CONGRESS AVE STE A LAKE WORTH FL, 33461 U.S.A	
	Phone #		Phone # 561-642-1247	
	Incident Status: New If update,include date of original submission	Location and date of incident. 06-14-2019	Date registrant became aware of incident. 07-01-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 65331-5	EPA Registration # (Product 2) 141-273	EPA Registration # (Product 3)
	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s) Vetmedin pimobendan chewable 1.25 mg NP	A.I. (s)
	Product 1 name FRONTLINE PLUS DOG 5-22 LBS	Product 2 name Vetmedin® (pimobendan) 1.25 mg Chewable Tablet	Product 3 name
	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?	Exposed to concentrate prior to dilution ?
	Formulation	Formulation Chewing tablet	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)).	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 : 12-Jul-2019 at 22:01

Internal ID # 19US038386

Brief description of incident circumstances

Suspected Adverse Event: On 1 Jul 2019 the pet owner reported the following event for Lola Bella, a 12 year old (born 20 Jun 2006), 8.1 pound, spayed female Maltese.
1 Oct 2006*: Started on HEARTGARD PLUS (68 MCG/57 MG) (lot and expiration unknown) and FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown) once monthly.
1 Jul 2007*: The canine was diagnosed with an unknown graded heart murmur.
3 Apr 2019: Started on VETMEDIN (PIMOBENDAN) 1.25 mg Chewable Tablet (lot and expiration unknown), 0.17 mg/kg, twice daily.
14 Jun 2019: The canine began exhibiting lethargy.
16 Jun 2019: Started on Benadryl once daily.
27 Jun 2019: The patient presented to the clinic and was hospitalized with suspected pneumonia. Upon performing a tracheal wash, the lungs began to bleed and the canine was diagnosed with an unknown form of cancer. A performed CBC indicated a low platelet count and the patient was humanely euthanized.
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: 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:	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Benadryl	List signs/symptoms/adverse effects Lethargy Neoplasia NOS Thrombocytopenia 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: 8.1 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 #

19US038386

Version : 12-Jul-2019 at 22:01

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter) Dr Erin WILSON	Internal ID # 19US038685
	Address Ex. 6 PP – personal address VERONA WI 53593 U.S.A		Address SPRING HARBOR ANIMAL HOSPITAL 5129 UNIVERSITY AVE MADISON WI, 53705 U.S.A	
	Phone # Ex. 6 PP – personal phone		Phone # 608-238-3461	

Row 1 Administrative Data	Incident Status: New If update,include date of original submission	Location and date of incident. 06-14-2019	Date registrant became aware of incident. 07-02-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 2126.RO	EPA Registration # (Product 2) 65331-5	EPA Registration # (Product 3)
	A.I. (s) RECOMBITEK LYME - 2126.RO	A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON	A.I. (s)
	Product 1 name RECOMBITEK LYME	Product 2 name FRONTLINE PLUS DOG 89-132 LBS	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)).	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 : 9-Sep-2019 at 16:24

Internal ID # 19US038685

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 2 Jul 2019, the pet owner reported the following event for Bill, a 3 year old, 97 pound, neutered male black Labrador Retriever.
19 Mar 2018, 12 Apr 2018, 1 Mar 2019: The dog was vaccinated with 1 mL RECOMBITEK LYME SC.
14 Jun 2019: The dog presented to the clinic experiencing lethargy and inappetance.
27 Jun 2019: The dog presented to the clinic with persistent lethargy and inappetance. The dog tested Lyme antigen positive on an unknown test and was additionally diagnosed with nephritis. Treatment was started with doxycycline, Enalapril and Omega 3 supplements.
The dog remains under treatment at this time. The dog has no prior history of Lyme testing. No further medical information expected.
UPDATE 15 Jul 2019: Dog is continuing to decline, bloodwork was performed with unknown results. No further information available at this time.
UPDATE 01 Aug 2019: Received records. 01 Mar 2019 RECOMBITEK LYME (42231, expiration 22 Oct 2020).
14 Jun 2019: Dog was treated with Vetprofen for 7 days for lethargy.
27 June 2019: creatinine 2.9 (0.5-1.8), BUN 30 (7-27), phosphorus 7.1 (2.5-6.8), albumin 2.0 (2.3-4.0), globulin 4.7 (2.5-4.4), ALP<10 (23-212), platelets 26 (148-484).
28 June 2019 UPC 12.6 (proteinuric).
02 July 2019 Quantitative C6 257 (>30 positive)
05 July 2019: SDMA 21 (0-14), creatinine 2.3, BUN 48, albumin 1.3, UPC 12.8
20 July 2019: SDMA 27, creatinine2.7, BUN 46, albumin 1.1, globulin 2.5, Red Blood cells 3.71 (5.39-8.7), platelets 49, UPC 12.9, USPG 1.021, 3+ hematuria and 4+ proteinuria.
30 July 2019: dog continues to be treated with benazepril and doxycycline. No further medical information is expected.
UPDATE 02 Aug 2019: Added owner address to contact screen.
UPDATE 8 Aug 2019: Per owner phone call, dog was on FRONTLINE(Unsubstantiated)(lot unknown, reporter not queried). The dates of usage are unknown. No further information is expected.
UPDATE 03 Sep 2019: Per owner, dog was euthanized due to
disease. 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: SC-subcutaneous	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) doxycycline, Enalapril,	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 millilitres per 1 animal Expose duration: 0 Day(s) Patient weight: 97 lbs			
Human severity category			

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

Internal ID #

19US038685

Version : 9-Sep-2019 at 16:24

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US042419
	Address Ex. 6 PP – personal address Covington Township PA 18444 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 12-02-2016	Date registrant became aware of incident. 07-11-2019	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)).	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 : 25-Jul-2019 at 15:31

Internal ID # 19US042419

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 11 Jul 2019, the pet owner reported the following event for Micah, a 10 year old, 14.5 pound, spayed female, Chihuahua Terrier Sheltie American Eskimo Mix.
1 Dec 2016*: She got her monthly dose of HEARTGARD PLUS(68 MCG/57 MG)(lot and expiration unknown) and FRONTLINE PLUS DOG 5 - 22 LBS(lot unknown).
2 Dec 2016*: The animal went to the clinic and was diagnosed with a unknown gallbladder disease, which had caused kidney failure.
24 Dec 2016: She passed.
The owner also reported another animal death case at this time, see case 19US042418. No further medical information expected.
UPDATE 24 Jul 2019: Per internal review, this case is a suspected adverse event not a suspected lack of efficacy as previously recorded. 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: 10 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 Gall bladder & bile duct disorder NOS Renal insufficiency 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: 13 Month(s) Patient weight: 14.5 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 #

19US042419

* approximate

Version : 25-Jul-2019 at 15:31

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 Unknown Unknown	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19JP000196
	Address Izumi Osaka Japan		Address --UNKNOWN--	
	Phone #		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 07-10-2019	Date registrant became aware of incident. 09-12-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 15 Sho-An 1977	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 M	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)).	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 : 18-Oct-2019 at 05:48

Internal ID # 19JP000196

Brief description of incident circumstances

As reported by the owner, on 08 Jul 2019, Frontline Plus (Lot number: unknown, Expiry date: unknown, Topical, dosage unknown) was administered to an 11 years and 8 months old, female, Bichon frise (BW: unknown, Reproductive status: unknown). The dog developed anorexia and loss of vigor two days later and was immediately brought to the hospital. According to the results of a blood test, an elevated level of hepatic function was observed. The dog had experienced elevated hepatic level several times before. Usually, the dog followed the course by displaying symptoms of vomiting at first, and then a treatment with intravenous drip and administration of drugs at the hospital was given for about 1 week and the symptoms resolved. However, the symptoms did not resolve this time and the dog died on 27 Aug 2019. The dog had a portosystemic shunt surgery at the age of 1 in the past. Although the dog developed transient convulsion after the surgery and was in a critical state, resolved recovery was achieved after a home care. Since the dog had good appetite and vigor prior to administration of Frontline Plus, the owner considers that the administration of Frontline Plus was a strain on the dog's liver and caused the death. UPDATE 16 Oct 2019: Following internal review, previously reported death was added to the VeDDRA coding.

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: 11.7 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: 2 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) drip infusion and	List signs/symptoms/adverse effects Anorexia Lethargy Elevated liver enzymes 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 #

19JP000196

Version : 18-Oct-2019 at 05:48

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19NZ000181
	Address Ex. 6 PP – personal address New Zealand		Address --UNKNOWN--	
	Phone #		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-05-2019	Date registrant became aware of incident. 09-02-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) A9009	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 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 Topicals	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)).	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 : 3-Sep-2019 at 07:39

Internal ID # 19NZ000181

Brief description of incident circumstances

As reported to me by the owner, approximately four weeks ago (5 August 2019) he treated his male neutered, 5.75kg Bichon Papillon cross dog with Frontline Plus for small dogs (FLP), batch and expiry unknown but during the past 2-3 weeks he has found fleas on his dog. He said he regularly treats his dog with FLP but was unable to provide treatment dates. There is only one dog in household, no cats and no change in environment or activity.

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: 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 Dose (1 unit) per 1 animal Expose duration: 0 Day(s) Patient weight: 5.7 kg			
Human severity category			

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

Internal ID #

19NZ000181

* approximate

Version : 3-Sep-2019 at 07:39

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19UK002143
	Address United Kingdom		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 07-07-2019	Date registrant became aware of incident. 07-10-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) Vm 08327/4270	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 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? 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 : 7-Aug-2019 at 11:28

Internal ID # 19UK002143

Brief description of incident circumstances

As reported by the animal owner, a male Bichon Frise dog aged 7 years and weighing 7 kg (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOG S (batch number S6032AL and expiry date JAN 2021) on 01 JUL 2019), by the dog's owner topically to the back of the neck by the animal owner as a parasiticide. The owner reported that the dog had a problem with fleas for some time and so tried FRONTLINE PLUS but in the 2 weeks since administration they had picked no less than 10 fleas off the dog. The owner also reported that they had powdered the house and sprayed the house and treated the dog several times but nothing seems to be working and felt very frustrated as they had spent £24 on the product. The owner asked for further advice on other treatments. In the house there is also one cat, two guinea pigs and one rabbit. The animal owner reports that they use Bob Martin products to treat the house (powder and spray) and the last time the dog and the cat were taken to the vets, neither of them had fleas. The dog, cat and rabbit are all given flea treatments all year round whether fleas are seen or not (product unknown) and the dog and cat wear flea collars all year round. The flea treatment used on Alfie prior to FRONTLINE PLUS (product unknown) was not working as Alfie still had fleas. Alfie had a bath before FRONTLINE PLUS was applied on 01 JUL 2019, then had another bath on 07 JUL 2019 because fleas were noticed, so another FRONTLINE PLUS was applied on the same day. Alfie was bathed again on 11 JUL 2019 as 5 fleas were removed from him last night (10 JUL 2019) and another 6 were removed during the bath. Alfie is mainly a house dog but goes outside to do his business, the cat comes and goes as he pleases but hasn't ever had fleas in the 8 years the animal owner has had him, the fleas only seem to have a taste for Alfie. The rabbit lives outside in a hutch and the guinea pigs live in the house in cages. The animal owner aims to bathe Alfie monthly but
when fleas are spotted he can be bathed more often as the animal owner removes the fleas off him better with flea shampoo. All bedding has been washed, both the animal owner's and Alfie's, and the living areas are sprayed overnight and the bedrooms are done during the day. The animal owner states that Alfie will still be scratching and biting himself until he is almost bald due to all the itching they cause.

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 : 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: 6 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Bathing, Frontline Plus	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: --UNKNOWN-- Expose duration: 0 Day(s) Patient weight: 7 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 #

19UK002143

Version : 7-Aug-2019 at 11:28

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19UK002854
	Address Ex. 6 PP – personal address United Kingdom		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-19-2019	Date registrant became aware of incident. 08-28-2019	Was incident part of larger study ? No

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) Vm 08327/4270	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 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? 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 : 19-Sep-2019 at 15:54

Internal ID # 19UK002854

Brief description of incident circumstances

As reported by the animal owner, Billy a male Bichon Frise dog aged 5.5 years and weighing less than 10 kg (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON DOG S, batch number: S60328AL, expiry date: JAN 2021, in JUN 2019 (further details unknown), by the animal owner, on an unknown date, as a parasiticide after seeing fleas. The owner reported that they are seriously concerned that FRONTLINE PLUS is not doing what it is advertised in their opinion. The owner has always owned dogs and they have never had one in all their years of owning them that has had fleas, but sadly this year their little Bichon picked up fleas either from the fields they assume they take him across or in the woods and parks near them. The owner was very concerned about this and was straight down to the pet shop to get some treatment for him. The owner is now on their second pack of FRONTLINE PLUS and are finding it does/did not kill fleas bearing in mind their little dog was not badly infested as they caught them, they thought straight away. The owner used the first pack as per instructions which didn't clear it so decided as we were advertising so much they would have to buy and try another pack of our expensive treatment. At the same time they were treating the house (product unknown), but it was the return of the fleas on the dog during the final treatment. The animal owner states that they have always had dogs but they have never had fleas, they use the product when they see fleas only, they first noticed fleas on their dog in JUN 2019 and this is also when they started using the product, and they have used the product according to the packet instructions. People in the home are not being bitten by fleas, the dog spends time indoors and outdoors, all animals in the home have been treated with a flea product, they are seeing occasional fleas (less than 5 at a time), the dog is regularly groomed by a professional groomer and this is not within 2 days of product
administration. The animal owner has not lived in the home for less than a year, the home has been treated with an environmental flea treatment (product unknown), the dog's bedding has been washed at over 60 degrees, and all areas the dog can access are regularly vacuumed.

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

Demographic information: Age: 5.5 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: Unknown	
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: per Unknown Expose duration: Patient weight: 10 kg*			
Human severity category			

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

Internal ID #

19UK002854

* approximate

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter) Dr Unknown	Internal ID # 19US043842
	Address Ex. 6 PP – personal address MIDDLETOWN OH 45044 U.S.A		Address ALL ABOUT PET CARE 3410 TYTUS AVE MIDDLETOWN OH, 45042 U.S.A	
	Phone # Ex. 6 PP – personal phone		Phone # 513-424-1626	
	Incident Status: New If update,include date of original submission	Location and date of incident. 07-22-2019	Date registrant became aware of incident. 07-25-2019	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)).	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 : 8-Aug-2019 at 20:41

Internal ID # 19US043842

Brief description of incident circumstances

Suspected Adverse Event:On 25 July 2019, the owner reported the following event for Fluffy, 14 years old, 11 pounds, spayed female, Bichon Frise/ Poodle crossbred.
21 July 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S61902AL) was applied between the shoulder blades, by the pet owner.
22 July 2019: The dog vomited more than once. The pet owner did noticed the dog had diarrhea and was anorexic.
23 July 2019: The dog continued to vomit.
24 July 2019: The dog recovered.
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: 14 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 Emesis Diarrhoea Anorexia		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: 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 #

19US043842

Version : 8-Aug-2019 at 20:41

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US047059
	Address Ex. 6 PP – personal address HOLMES PA 19043 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-07-2019	Date registrant became aware of incident. 08-07-2019	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? 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 : 20-Aug-2019 at 17:09

Internal ID # 19US047059

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 7 Aug 2019, the pet owner reported the following event for Logan, a 5 year old, 12 pound*, neutered male, Bichon Frise.
Unknown dates: At around 9 weeks of age, the canine began receiving one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) applied topically from the base of the skull down to at least the shoulder blades. One vial has since been applied topically in the same fashion, monthly between the twentieth and the twenty-fifth, year-round. Since an unknown date, Logan is also bathed with an unknown product and groomed every 5 weeks.
Jun 2019 (unknown date): Six vials of FRONTLINE PLUS DOG 5-22 LBS (S63009) were purchased from a local retailer.
23 Jun 2019* and 23 Jul 2019*: One vial of FRONTLINE PLUS DOG 5-22 LBS was applied to Logan in the same manner as previously described.
7 Aug 2019: After being dropped off at the groomer's, the groomer found a single living flea and an unknown amount of flea dirt on Logan. He has since been bathed with an unknown product, but it's unknown if the issue remains ongoing.
The reporter was unable to provide much information regarding Logan's external environment. He states that Logan has never had fleas on him until today and he's finding no evidence of fleas in the home. There are no other animals in the home nor have any visited. No further medical information expected.
UPDATE 15 Aug 2019: Per the pet owner, he reapplied one vial of FRONTLINE PLUS DOG 5-22 LBS in the same manner as previously described on 14 Aug 2019. The status of the canine is unknown. 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: 5 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: 15 Day(s) *	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) bath with unknown product	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: 22 Day(s) Patient weight: 12 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 #

19US047059

* approximate

Version : 20-Aug-2019 at 17:09

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 Sue Unknown	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US047550
	Address U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-08-2019	Date registrant became aware of incident. 08-08-2019	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? 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 : 26-Aug-2019 at 19:31

Internal ID # 19US047550

Brief description of incident circumstances

Suspected Adverse Event: On 08 Aug 2019, animal owner reported the folloiwng event for a Bichon Frise. All signalment is unknown.
05 Aug 2019: A dose of FRONTLINE PLUS DOG 5-22 LBS (Lot unknown) was applied.
08 Aug 2019: The pet owner noticed the dogs fur changed to a yellow color at the application site.
The pet owner received the product from Canada. All additional information is unknown.
UPDATE: 21 Aug 2019: Pet owner called back to provide additional details: The owner reported her vet friend researched the product information and the box stated South Africa and they determined it was conterfeit product (reported in 19US050650) and discarded the remaining 11 doses. The dog was bathed and the owner noted the yellow stain came off and the dog is back to normal. The pet owner denied initially stating anything about Canada. She did confirm she got the product from a friend who initially purchased the product and received the wrong size so she gave the product to reporter.

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: 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 Application site hair change		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-D			

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

Internal ID #

19US047550

Version : 26-Aug-2019 at 19:31

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US047909
	Address U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-10-2019	Date registrant became aware of incident. 08-12-2019	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)).	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 : 26-Aug-2019 at 01:33

Internal ID # 19US047909

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 12 Aug 2019 a pet owner reported the following event for Jack, a 10 pound, male Bichon Frise of unkown age and reporductive status.
6 Aug 2019: Owner applied FRONTLINE PLUS DOG 5-22 LBS (lot unknown, package unavailable) to the skin between the animal's shoulder blades for the first time in an unknown amount of months.
7 Aug 2019: Approximately 12 hours later the dog was bathed at the groomer with oatmeal shampoo.
10 Aug 2019*: Owner saw more than 10 fleas on the dog for the first time.
11 Aug 2019: Owner bathed dog with a flea shampoo and saw 2 fleas.
12 Aug 2019: Owner is seeing more than 10 fleas on the dog.
There are no fleas in the home. The owner has another dog in the home who had fleas prior to 6 Aug 2019. There are no other details known as the pet owner feels the product did not work becasse it was washed off during the grooming less than 24 hours after application.
UPDATE 23 Aug 2019: Product problem type was changed to LOE per case type.

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: 4 Day(s)	
Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) Unknown flea 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: 0 Day(s) Patient weight: 10 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 #

19US047909

Version : 26-Aug-2019 at 01:33

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US053222
	Address Ex. 6 PP – personal address CAMPBELL OH 44405 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-01-2019	Date registrant became aware of incident. 09-05-2019	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 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)).	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 : 19-Sep-2019 at 18:19

Internal ID # 19US053222

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: 05 Sep 2019: An owner reported the following event in Trixie, an 8 year old, 13 pound, spayed, female, Bichon Frise.
19 May 2019: The owner administered one FRONTLINE PLUS DOGS 5-22 LBS (S62502AW) topically in-between the shoulders for the first time this year. No fleas were seen at the time of application.
21 Jun 2019*, 25 Jul 2019*, 31 Aug 2019: The owner administered one dose topically in-between the shoulders. No fleas were seen at the time of application.
01 Sep 2019: The owner saw 6 fleas. There are no other animals in the home. The dog is groomed every 5 weeks and bathed at home in normal dog shampoo every few weeks. The dog is indoor-outdoor in an unknown environment. The dog has received the product seasonally for 8 years with no previous events. 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: 8 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 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: 13 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 #

19US053222

Version : 19-Sep-2019 at 18:19

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US053812
	Address PA U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 08-19-2019	Date registrant became aware of incident. 09-09-2019	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)).	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 : 20-Sep-2019 at 20:33

Internal ID # 19US053812

Brief description of incident circumstances

Suspected Lack of Efficacy Claim: On 9 Sep 2019 a pet owner reported the following event for a 15 pound, 3.5 year old, female Bichon Frise/Yorkshire Terrier cross.
1 Aug 2019 and 1 Sep 2019: Owner applied FRONTLINE PLUS DOG 5-22 LBS (lot unknown, Package unavailable) to the skin between the animal's shoulder blades.
19 Aug 2019*: Owner started seeing 2-3 fleas on the dog daily after returning home from the groomer.
Dog goes in the front yard to potty. Some squirrels have been seen in the yard. Owner treats the yard every 3 months, but has not treated the home.
Bathes dog in flea shampoo every 3 weeks. No fleas seen on humans or in the home. There are no other animals in the home. The owner has not had a problems with fleas before this event. The owner has been applying FRONTLINE to the dog monthly since 2016*. 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: 3.5 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: 18 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 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 #

19US053812

Version : 20-Sep-2019 at 20:33

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 Ex. 6 PP – personal name	Submission date. 10-25-2019	Contact person (if different than reporter)	Internal ID # 19US053464
	Address Ex. 6 PP – personal address PORTSMOUTH NH 03801 U.S.A		Address --UNKNOWN--	
	Phone # Ex. 6 PP – personal phone		Phone #	
	Incident Status: New If update,include date of original submission	Location and date of incident. 09-03-2019	Date registrant became aware of incident. 09-06-2019	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)).	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 : 19-Sep-2019 at 22:05

Internal ID # 19US053464

Brief description of incident circumstances

Suspected Lack of Efficacy Claim and Adverse Event: On 6 Sep 2019, the pet owner reported the following event for Daisy, a 6 year old, 28 pound, spayed female, Bichon Frise.
1 Aug 2019*:Fleas were noticed prior to FRONTLINE dose.
2 Sep 2019: The patient got their dose of FRONTLINE PLUS DOG 23-44 LBS(S63019AL). This was the first dose ever. The owner purchased a 3 pack this past purchase. It was applied between the shoulder blades.
3 Sep 2019*: The owner noticed fleas were still present, but far less than before FRONTLINE.
4 Sep 2019*: The fur at the application site was yellowish. No treatments or clinical visits have been sought for this.
The pet goes outside daily. The owner bathes the pet, randomly with an unknown shampoo last time was 2 weeks ago. There are no fleas in the home, and no fleas on the owner.
The patient's current condition is ongoing.
No further medical information expected.

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: 6 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 Application site hair change 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: 28 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 #

19US053464

Version : 19-Sep-2019 at 22:05

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 6:28:26 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_EPAAggregateReport3Q19) 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_003375
Sec3-6(a)(2)-000002: CDX_2021_003376
Sec3-6(a)(2)-000003: CDX_2021_003377
Sec3-6(a)(2)-000004: CDX_2021_003378
Sec3-6(a)(2)-000005: CDX_2021_003379

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.

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