Alicia Henk
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T027223

November 26, 2014

Documents Processing Desk – 6(a)(2)
U.S. Environmental Protection Agency
Office of Pesticides Programs
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: FIFRA Section 6(a)(2) Report
Ceva Animal Health, LLC – Company Number 83399

Dear Sir/Madam:

Enclosed is a copy of the 3rd Quarter (Jul-Sep) 2014 summary report for Ceva Animal Health, LLC for the following product registrations:

- SVP-7 Vectra 3D and SimpleGuard3, EPA Registration No. 83399-6; also sub-registered as First Shield Trio, EPA Registration No. 83399-6-85581
- SVP-8 Vectra for Cats, Vectra for Cats and Kittens, and SimpleGuard for Cats and Kittens, EPA Registration No. 83399-9; also sub-registered as First Shield for Cats, EPA Registration No. 83399-9-85581
- SVP-9 Vectra for Dogs and Puppies, EPA Registration No. 83399-10; also sub-registered as First Shield Dog and Puppy, EPA Registration No. 83399-10-85581

We trust this information satisfies EPA FIFRA Section 6(a)(2) reporting requirements. Please contact me by phone at 913-754-7668 or by e-mail at alicia.henk@ceva.com if additional information is required.

Sincerely,

Alicia Henk
Director,
Development and Pharmaceutical Regulatory Affairs

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CC: California Department of Pesticide Registrations
Adverse Effects Reporting
1001 I Street
P.O. Box 4015
Sacramento, CA 95812-4015

New York Department of Environmental Conservation
Office of Pesticides
625 Broadway
Albany, NY 12233-4500

EPA
11-28-14

FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2014
EPA Reg. No.: 83399-12

Submission Date: November 26, 2014
Page: 1 of 1

Product Name: Vectra Pro Flea Spray

Active Ingredients: Dinotefuran

-001

	Exposure Types and Severity Category Designations						
Total Incidents	**H-D**	**H-E**	**D-A**	**D-B**	**D-C**	**D-D**	**D-E**
1	0	0	0	0	0	1	0

FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2014

Submission Date: November 26, 2014

EPA Reg. No.: 83399-9

Page: 1 of 1

Product Name: Vectra for Cats/ Vectra for Cats and Kittens

Active Ingredients: Dinotefuran, Pyriproxyfen

-002

	Exposure Types and Severity Category Designations						
Total Incidents	**H-D**	**H-E**	**D-A**	**D-B**	**D-C**	**D-D**	**D-E**
55	0	0	1[A]	0	3	50	1

ADDITIONAL INFORMATION:

[A] Notes on D-A:
Case # 2014-US-002168 - On 11 Aug 14, "Mindy" (6 lb, 16 yr, f/s, Domestic Long Hair cat) in unknown health condition, with no previous medical problems, had Vectra for Cats and Kittens 3-9 lb (lot # unspecified, single dose) applied via spot method, by the pet owner for flea prevention. There were no concomitant products administered. This product had been applied to this cat previously, on an unspecified date, and no adverse effects were noted. Two hours post application; the cat exhibited foaming at the mouth, seizure like activity, and death. The cat was not examined by the veterinarian and no necropsy was performed. As no diagnostics were performed, it is difficult to determine the role the product played in the causality of the clinical sign(s). The case is medically closed.

FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2014

Submission Date: Novmeber 26, 2014

EPA Reg. No.: 83399-10

Page: 1 of 1

Product Name: Vectra for Dogs and Puppies

Active Ingredients: Dinotefuran, Pyriproxyfen

-003

	Exposure Types and Severity Category Designations						
Total Incidents	**H-D**	**H-E**	**D-A**	**D-B**	**D-C**	**D-D**	**D-E**
8	1	0	0	0	1	6	0

FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2014

Submission Date: November 26, 2014

EPA Reg. No.: 83399-6

Page: 1 of 2

Product Name: Vectra 3D

Active Ingredients: Dinotefuran, Pyriproxyfen, Permethrin

-004

	Exposure Types and Severity Category Designations						
Total Incidents	**H-D**	**H-E**	**D-A**	**D-B**	**D-C**	**D-D**	**D-E**
489	39	0	5[A]	9	36	395	5

ADDITIONAL INFORMATION:

[A] Notes for D-A: -

Case # 2014-US-002396 - On 03 Aug 14, the pet owner applied several drops of Vectra 3D for Dog and Puppies 56-95 lb (lot #unspecified, single dose) to "Precious" (2 lb, 17 week, F, Domestic Short Hair cat). The owner unknowingly applied the incorrect product to her cat for flea prevention. It is unknown if there were concomitant products administered. Two hours post application, the cat was presented to the veterinarian exhibiting tremors and seizures. The pet was treated with methocarbamol, midazolam, atropine and IV Fluids. The kitten did not recover and died. There was no necropsy performed. This product was used off label on the incorrect species. The product is not labeled to be used on cats. This case is medically closed.

Case # 2014-US-002397 - On 03 Sept 14, the owner applied Vectra 3D for dogs and puppies 56-95 lb (lot #unspecified, single dose) topically, to one of her outdoor cats "Unspecified Name" (age, weight, sex, breed unspecified) in unknown health condition. There were no concomitant products administered. The owner unknowingly applied the incorrect product to her cat for flea prevention. On 03 Sept 14, at an unknown time frame post application, the owner found the cat which died. This product was used off label on the incorrect species. The product is not labeled to be used on cats. Case is closed.

Case # 2014-US-002634 – On 26 Sep 14, the staff at the humane society applied a few drops of Vectra 3D >95# (lot#1312800) to "unknown name" (Domestic Shorthair cat, 10 weeks, 1.0 kg, unknown sex) in unknown health condition. The product was applied accidently. It is unknown if there were concomitant medications administered. Five hours post application, the kitten exhibited tremors, and severe seizures. The kitten was examined by the veterinarian on 26 Sep 14, and treated with Robaxin, Valium, phenobarbital, and propofol. The kitten did not respond to any treatment and was euthanized twelve hours post application. There were no diagnostic tests or necropsy performed. The case is medically closed.

Case # 2014-US-002215 – On 14 Aug 14, the owner applied Vectra 3D 56-95# (lot# unspecified) to Baby (Domestic Long Hair cat, F, 8 months, 4 lb) in fair health, with a history of grade IV-V heart murmur, accidentally for flea prevention. The owner realized immediately that she had applied the wrong product to the cat and wiped the application area with a wet rag. There were no concomitant products administered. Two hours post application, the cat exhibited tremors. It is unknown if any treatment was performed. The cat died five hours post application. There was no necropsy performed. Cats do not tolerate permethrin. Signs range from mild dermal hypersensitivity to seizures. Signs can develop immediately up to 72 hours post-exposure. Case is medically closed as the owner declined follow up.

Case # 2014-US-2187 - On an unspecified date in August 2014, Major (9yr, F/S, 64.9#, Labradoodle/Australian Shepherd mix) in fair condition had Vectra 3D 56-95# (Lot# unspecified, 3pk) in fair condition, with history of azotemia, applied topically by the owner for flea and tick prevention. This dog was applied six previous doses of this product and no adverse effects were noted. There were no concomitant products administered. On 23 May 14, on a routine recheck exam prior to application of the product, blood work results show continued mild azotemia. On 11 Aug 14, the dog presented to the clinic in cardiac failure and the owner elected euthanasia. There was no necropsy performed. The attending veterinarian's opinion regarding this event is that it is unlikely the product was causal. Additionally, the animal's medical history could have contributed to the reported clinical signs. The case is closed due to lack of medical information by the owner after numerous attempts via phone calls.

FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2014

Submission Date: November 26, 2014

EPA Reg. No.: 83399-9-85581

Page: 1 of 1

Product Name: FirstShield for Cats/ FirstShield for Cats and Kittens

Active Ingredients: Dinotefuran, Pyriproxyfen

-005

	Exposure Types and Severity Category Designations						
Total Incidents	**H-D**	**H-E**	**D-A**	**D-B**	**D-C**	**D-D**	**D-E**
8	0	0	1[A]	0	1	6	0

ADDITIONAL INFORMATION:

[A] Notes for D-A:
2014-US-001650 - On 30 Jun 14, Nala (5yr, F/S, 15#, Domestic Short hair cat) in good condition, with no previous medical history, had First Shield for Cats >9# (Lot#ANP, single dose) applied topically by the owner for flea prevention. There were no concomitant products administered. The owner purchased First Shield Trio > 95 lbs from the veterinarian, for the family dog, at the same time. Within twelve hours post application, the cat exhibited seizures. On 30 Jun 14, the owner took the cat to the University of Pennsylvania Veterinary Hospital for examination, however the owner declined any treatment due to cost restraints. The owner made the decision to have the cat euthanized. There was no necropsy performed. The reported events are not typical or known to occur with the use of the product and it is difficult to determine what role, if any, the product played in the event. Case is medically closed.

FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2014

Submission Date: November 26, 2014

EPA Reg. No.: 83399-10-85581

Page: 1 of 1

Product Name: First Shield for Dogs and Puppies

Active Ingredients: Dinotefuran, Pyriproxyfen

-006

	Exposure Types and Severity Category Designations						
Total Incidents	**H-D**	**H-E**	**D-A**	**D-B**	**D-C**	**D-D**	**D-E**
3	1	0	0	0		2	0

FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2014

Submission Date: November 26, 2014

EPA Reg. No.: 83399-6-85581

Page: 1 of 1

Product Name: First Shield Trio

Active Ingredients: Dinotefuran, Pyriproxyfen, Permethrin

-007

	Exposure Types and Severity Category Designations						
Total Incidents	**H-D**	**H-E**	**D-A**	**D-B**	**D-C**	**D-D**	**D-E**
87	11	0	0	2	10	64	0

FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2014

Submission Date: November 26, 2014

EPA Reg. No.: 83399-9

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Product Name: Simple Guard for Cats and Kittens

Active Ingredients: Dinotefuran, Pyriproxyfen

-008

	Exposure Types and Severity Category Designations						
Total Incidents	**H-D**	**H-E**	**D-A**	**D-B**	**D-C**	**D-D**	**D-E**
6	0	0	0	0	1	5	0

FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2014

Submission Date: November 26, 2014

EPA Reg. No.: 83399-6

Page: 1 of 1

Product Name: Simple Guard 3

Active Ingredients: Dinotefuran, Pyriproxyfen, Permethrin

-009

	Exposure Types and Severity Category Designations						
Total Incidents	**H-D**	**H-E**	**D-A**	**D-B**	**D-C**	**D-D**	**D-E**
62	1	0	1[A]	0	2	57	1

[A] Notes for D-A:
Case # 2014-US-001694 - On 27 Jun 14, the owner applied Simple Guard 3 21-55# (lot# unspecified), to the family dog and kept him/her separated from the patient for approximately three hours. Sweet Pea (Domestic cat, F/S, 16 yr, 8 lb) in fair condition, with a history of Bowen's disease, has a somewhat friendly relationship with the family dog. The cat has a history of grooming the dog's head. On 04 Jul 14, six days post application of this product, to the dog, the cat was observed by the pet sitter exhibiting hypersalivation, vocalization, disorientation, and restlessness. On 05 Jul 14, the cat was dead. There was no treatment administered, and no diagnostics performed. There was no necropsy performed, and the cat was buried by the owner on 06 Jul 14. Cats are very sensitive to permethrin. Adverse signs expected are tremors, ataxia, depression, vomiting, seizures, and death. Case is medically closed.