2517-148

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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES 0170

February 21, 2012

James B. Messina, Principal Regulatory Consultant (Authorized Agent for Sergeant's Pet Care Products, Inc.) Exponent Center for Chemical Regulation and Food Safety 1150 Connecticut Avenue, N.W. Suite 1100 Washington, DC 20036

Subject: Revise CRP labeling (Net Content, Opening and directions).

- Sergeant's Fipronil Spot-On for Cats EPA Reg. No. 2517-137
- Sergeant's Fipronil + Methoprene Spot-On for cats EPA Reg. No. 2517-135
- Sergeant's Fipronil + Etofenprox + Methoprene Spot-On for Cats EPA Reg. No. 2517-145
- Sergeant's Fipronil + Pyriproxyfen Spot-On for Cats EPA Reg. No. 2517-146
- Sergeant's Fipronil + Etofenprox + Pyriproxyfen Spot-On for Cats EPA Reg. No. 25 17-147
- Sergeant's Fipronil + Etofenprox Spot-On for Cats EPA Reg. No. 2517-148

Applications dated September 26, 2011

Dear Mr. Messina:

The above referenced labeling for each of the subject products, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable:

Please note that we have approved the amended labels for these products with the understanding that they are consistent with the Agency's previously stamped accepted ones; and other than the revisions stated in your applications (dated September 26, 2011), no other changes have been made to the labeling and/or the Confidential Statement of Formula (CSF).

See enclosed copy of the stamped label for your record. If you have any questions concerning this action please contact me or Dr. B.A. Akinlosotu (703-605-0653 or via email Akinlosotu.bonaventure@epa.gov).

Sincerely,



Richard Gebken, Product Manager 10 Insecticide Branch Registration Division (7505P)

		30910
Serge	ant's <sup>®</sup> Master L	abel
26 Sep 2011 Amendment Information in [] is optional.	Version 10.6 Page 1 of 8	EPA Reg. No. 2517-148 EPA SAL 8/18/2011
[Optional text appears in brackets-the	final label may include some or back or side label panels.]	c all of the optional text on the front,
FRONT PANEL		CAT SPOT ON
Sorgoant's Fin	ranil + Etafannyay Sna	FIPRONIL+ETOFENPROX
[ABNs:]	ronil + Etofenprox Spo	n On for Cats
[(Sergeant's <sup>®</sup> ) (Sentry <sup>®</sup> ) FRONT] [(Sergeant's <sup>®</sup> ) (Sentry <sup>®</sup> ) Ectoadva [(Sergeant's <sup>®</sup> ) (Sentry <sup>®</sup> ) Frontspo [(Sergeant's <sup>®</sup> ) (Sentry <sup>®</sup> ) Frontspo [(Sergeant's <sup>®</sup> ) (Sentry <sup>®</sup> ) Frontgua [(Sergeant's <sup>®</sup> ) (Sentry <sup>®</sup> ) Fiproline [(Sergeant's <sup>®</sup> ) (Sentry <sup>®</sup> ) Advansp [[Sergeant's <sup>®</sup> ][SENTRY <sup>®</sup> ] Adva [[Sergeant's <sup>®</sup> ][SENTRY <sup>®</sup> ] PROJ [[Sergeant's <sup>®</sup> ][SENTRY <sup>®</sup> ] FIPR [Apply to kittens over 12 weeks of der [For use ONLY on cats [[&][and] k	ance <sup>TM</sup> (Spot On) for cats] ot <sup>TM</sup> (Spot On) for cats] (Spot On) for cats] ge (Spot On) for cats] ard <sup>TM</sup> (Spot On) for cats] onil (Spot On) for cats] e (Spot On) for cats] tot (Spot On) for cats] nSpot PLUS for cats] NYL OTC <sup>TM</sup> Max for cats] OGUARD <sup>TM</sup> Max for cats]	ACCEPTED FEB & 1 2012 Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:
[For use ONLY on cats] [of ALL w [Mosquitoes]	eights] [over 12 weeks of ag	ge]
[•Kills mosquitoes] [Chewing Lice] [•Kills chewing lice] [•Fast Action against chewing	ng lice infestations]	
[Adult Fleas] [• [Full or Partial Brand Nar [•Kills Fleas [Up to [4] [6] w [•Kills Fleas that may cause infestation] [•Stops and prevents reinfess [•Controls flea reinfestation [• [Full or Partial Brand Nar [•If cat is a high risk for flea [•Prevents and controls reinf	veeks]!] flea allergy dermatitis, flea tation] [for up to six weeks]] ne] kills adult fleas for up to reinfestation a once month	bite anemia, and tapeworm
[Ticks] [•Kills Ticks including those [•Kills Ticks for Up to [4 we [•Kills Deer Ticks (which m days]]	eeks]!]	sease] for up to [4 weeks] [1 month][30

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[•Kills Ticks (Including Dee [•Kills [American Dog Ticks [•Kills [Brown], [American] [•Kills American Dog Ticks	s for up to 4 weeks]] [and Lone Star] dog ticks f	
		effective flea, tick, [and] chewin
lice [and mosquito] control f [•Controls reinfestation for u [• Flea & Tick Control for C	up to four weeks]	
[•Kills fleas, ticks, [&] chew		
[•Kills fleas, ticks, [mosquite	oes,] and chewing lice]	· ·
[•Monthly flea, tick, [mosqu		ction]
[•[4 Week] [Flea and Tick ]		1. 0 ( 11)
[•[Four (4) Week] [Flea Tick		
[•[Four] [4][Three][3] Way I [•Once A Month Flea and Ti		3 3 3 3 3 3
[•Kills Fleas and Ticks for u		202 2000
•Starts to kill fleas and ticks		ll for a month
[•Kills [fleas] in 4 hours [and		3 3
	e] kills fleas in 4 hours and	Dermacentor ticks in one hour]
[•Kills ticks in 1 hour]		
[•Kills fleas and ticks in [24		
[•Starts killing fleas and tick	s in as little as 1 hourj	
[All Others]		
[•Stops and prevents infestat	tions]	
[•For Cats and Kittens 12 we	-	
[•Fast Acting]		
[•Cats can be bathed 24 hour	rs after treatment]	
[•Waterproof]		
[•Long Lasting]		
Applications][Six Application [1 Month Supply][Two Month Month Supply][6 Month Supply][8 Week Supply][12 Week Supply][48 Week Sup	ons][Twelve Applications][" th Supply][3 Month Supply oply][12 Month Supply][X I Week Supply][16 Week Su	Month Supply] or [4 Week upply][Twenty Week Supply][24
[• Best if used year round!]		
[• (ICON Showing 4 Week I	Protection)]	
[• 4 Week Dose!]		
[• 1 Month Dose!] [• Easy to Use Application]		
[• Specially Formulated for (	Cats and Kittens [12 weeks	or older]]
[• [Free] Calendar Stickers In		or order 11
[• [Free] Brochure Inside!]		
[• [Free] Brochure and Caler	ndar Stickers Inside]	
	1	

Sergea	ant's <sup>®</sup> Master L	abel	
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Information in [] is optional.	Page 3 of 8	EPA SAL 8/18	/2011
[• Apply once every [4 weeks [• Convenient to use] [• [Free with purchase] [Free [insert]] [•Patent Pending] [•[1][2][3][4][5][6][12][24] A ACTIVE INGREDIENTS: Fipronil Etofenprox OTHER INGREDIENT[**] TOTAL:	[month] [30 days]!] inside] Monthly Application Applications] 	n Reminder [Magnet] 0% 0% <u>0 %</u>	
[**diethylene glycol monoeth	vl ether]		3 3
KEEP OU	JT OF REACH OF CHILI CAUTION anel] For Additional Preca	000000	000000 0 00000 0 00000 0 00000
NET CONTENTS:			2
[1][One][2][Two][3][Three][4][Fou 0.017 fl oz [0.50 ml] applicators	r][5][Five][6][Six][12][Tw	elve][24][Twenty-Fo	ur]

#### [BACK/SIDE CARTON LABEL - MASTER LABEL]

[Full or Partial Brand Name] contains Fipronil and Etofenprox to effectively kill fleas, ticks, [mosquitoes] and chewing lice. The active ingredients in [Full or Partial Brand Name] features a sustained-release formula developed for fast-acting [and long-lasting] control of fleas, ticks, [mosquitoes] and chewing lice [for 30 days] on cats [and kittens 12 weeks or older].

### READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON CATS AND KITTENS OVER 12 WEEKS OF AGE.

#### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS. CAUTION.** Causes moderate eye irritation. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Harmful if swallowed. Harmful if absorbed through skin.

**HAZARDS TO DOMESTIC ANIMALS**. For external use only. Do not use on kittens under 12 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-224-PETS [7387] for 24-hour assistance.

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	FIRST AID
If In Eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
If On Skin Or Clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
If Swallowed	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
<u> </u>	
treatment. For n	ct container or label with you when calling a poison control center or doctor, or going for nore information on this pesticide product (including health concerns, medical pesticide incidents), you may call 1-800-781-4738.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

### READ ENTIRE LABEL BEFORE EACH USE.

FOR EXTERNAL USE ON CATS ONLY. Do not use on kittens under 12 weeks of age. Use entire contents of tube [vial] on each cat. [Do not split tubes between cats.] [Do not use multiple tubes on one cat.] Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. **Best if used year round**. Consult a veterinarian before using this product on debilitated, aged, medicated cats. Consult a veterinarian before using on cats with known organ dysfunction. Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied. Cats and dogs that actively groom or engage in close physical contact with treated cat may be at risk of serious harmful effects. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your pet for the next 24 hours.

Sensitivities may occur after using ANY pesticide product on cats. If signs of sensitivity occur bathe your cat with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately by calling 1-800-781-4738.

[Optional diagram may or may not appear anywhere on the finished label]





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.....

[{Outer Packaging}]

**How to open:** Remove product tube(s) *[vial]* from the package. [Separate one tube from the others.] Hold the tube *[vial]* with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to apply: While holding the cat with one hand, use the other hand to apply the solution. Invert the tube *[vial]* and use the narrow end to part the cat's hair. Apply contents of one tube *[vial]* of **{Full or Partial Brand Name}** [as a stripe, starting high on the back of the cat's neck to in front of the shoulder blades] [as a spot between the shoulder blades]. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat. When finished, wrap the tube *[vial]* in paper and put into the trash. Only one applicator per treatment is needed.

#### FREQUENCY OF APPLICATION

Use [Full or Partial Brand Name] monthly for complete control of flea, tick [and] chewing lice [and mosquito] infestations. [Full or Partial Brand Name] kills fleas for up to six weeks. Apply monthly, if your pet is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks, [mosquitoes] and chewing lice. [[Full or Partial Brand Name] kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 28 days.] [Full or Partial Brand Name] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

### STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Do not remove tube from the pack until ready to use. Store in a cool (below 77°F[/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

**CONTAINER DISPOSAL: If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

#### [WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. [The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer.] Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

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[If you have questions or comments about this product, please write: Sergeant's Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

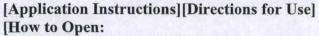
In Case of Emergency, call: 1-800-781-4738 Non-Emergency call 1-800-224-PETS (7387) [Made in USA]

Distributed by: Sergeant's Pet Care Products, Inc. P.O. Box 540399 Omaha, NE 68154-0399 EPA Reg. No. 2517-148 EPA Est. No. XXXXX -XX -XXX

[BAR CODE AREA]

# **{START - OPTIONAL INSERT OR PACKAGE COPY}**

[• How to Apply - May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a vial on front, side, or back carton label and/or. applicator labeling.]



- 1. Remove product tube(s) [vial] from the package.
- 2. [Separate one tube from the others.] Hold the tube *[vial]* with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

#### How to Apply:

- 1. Invert tube over cat and use open end to part cat's hair.
- 2. Apply contents of one tube *[vial]* of {Full or Partial Brand Name} [as a stripe, starting high on the back of the cat's neck to in front of the shoulder blades] [as a spot between the shoulder blades]. Squeeze tube firmly to apply all of the solution to the cat's skin.]

[Optional diagram may or may not appear anywhere on the finished label]









ADULT FLEA FLEA FURAE FLEA PURAE

[Flea life cycle diagram]

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[Easy][Spot On] [Squeeze-On] [Topical] Checklist

- [1] Read the label completely and follow directions
- [2] Weigh your pet
- [3] Do NOT use Dog products on Cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after treatment to avoid chance of ingestion
- [6] Do NOT split tubes between pets][and use the entire tube contents]

### [Full or Partial Brand Name]

[Monthly reminder card]

[Apply [Full or Partial Brand Name] monthly for continuous protection against fleas, ticks [and] chewing lice [and mosquitoes].]

[Pet's Name (Empty blank for owner to fill in name)]

[First [dose] [Treatment] (Empty blank for owner to fill in date)] [Second [dose] [Treatment] (Empty blank for owner to fill in date)] [Third [dose] [Treatment] (Empty blank for owner to fill in date)] [Fourth [dose] [Treatment] (Empty blank for owner to fill in date)] [Fifth [dose] [Treatment] (Empty blank for owner to fill in date)] [Sixth [dose] [Treatment] (Empty blank for owner to fill in date)] [Seventh [dose] [Treatment] (Empty blank for owner to fill in date)] [Eighth [dose] [Treatment] (Empty blank for owner to fill in date)] [Eighth [dose] [Treatment] (Empty blank for owner to fill in date)] [Ninth [dose] [Treatment] (Empty blank for owner to fill in date)] [Tenth [dose] [Treatment] (Empty blank for owner to fill in date)] [Eleventh [dose] [Treatment] (Empty blank for owner to fill in date)]

[Twelfth [dose] [Treatment] (Empty blank for owner to fill in date)]

[calendar stickers with Full or Partial Brand Name] [Place stickers on your calendar as a reminder to reapply [Full or Partial Brand Name] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)

Enclosed for your convenience is an application reminder magnet. Push the (reset) button to start the clock. After 30 days the magnet will flash (and beep) reminding you to reapply [Full or Partial Brand Name]. This application reminder can be used for future treatments. Just press the reset button and in another 30 days the reminder magnet will flash (and beep) reminding you to reapply.]

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[Optional graphics which may or may not appear anywhere on the finished label]

🗩 Fleas	Reas
Ticks	Ticks
↗► Mosquitoes	Mosquitoes
Thewing Lice	Chewing Lice

# **{END - OPTIONAL INSERT OR PACKAGE COPY}** [TUBE] [VIAL] LABEL

Front Label	Back Label	
{Brand Name} [For use only on cats/kittens	KEEP OUT OF REACH OF CHILDREN	
12 weeks or older]	CAUTION: Read directions and precautions	
Fipronil 9.8% w/w, Etofenprox 15% w/w	before using. Use scissors to open.	
0.017 fl oz [0.50 mL] {label code}	EPA REG. No. 2517-148 {label code}	
	. 22223 1	-