

2517-137

5/29/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 29, 2012

Kelly R. Hoskins,
Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-1710

Subject: Notifications "to add optional graphics to label with appropriate text".

Sergeant's Fipronil Squeeze-on for Dogs (EPA Reg. No. 2517-136)
✓ Sergeant's Fipronil Spot-on for Cats (EPA Reg. No. 2517-137)
Date of Applications: February 28, 2012

Dear Mr. Hopkins:

The Agency is in receipt of your Applications for Pesticide Notification under Pesticide Registration (PR) Notice 98-10 for the subject product. The Registration Division (RD), after conducting a review of each request for its applicability, finds that the action(s) requested fall(s) within the scope of the subject notice.

Please note that we have approved the amended labeling for each product with the understanding that it is consistent with the Agency's previously stamped accepted label(s); and other than the above stated, no other changes have been made to the labeling and/or the Confidential Statement of Formula (CSF).

The label submitted with each application have been stamped "Notification" and will be placed in our records. If you have any questions regarding this letter, please contact me or Dr. B. A. Akinlosotu at (703) 605-0653.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

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



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138-3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

February 28, 2012

Richard Gebken, PM10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Application for Pesticide Notification (Label Revision) for
Sergeant's Fipronil Spot-on for Cats (EPA Reg. No. 2517-137)

Dear Mr. Gebken:

Sergeant's Pet Care Products, Inc. (Sergeants, 10077 South 134th St, Omaha, NE 68138-1710, EPA Company Number 2517) is submitting a notification of revision to the master label for the end-use product Sergeant's Fipronil Spot-on for Cats (EPA Reg. No. 2517-137), containing the active ingredient fipronil. The following items are enclosed in support of this notification:

- Application for Pesticide Notification, EPA 8570-1 form; and
- Master Label v. 12.1 (2 copies, 1 with changes highlighted).

Sergeant's is submitting this notification to add optional graphics to the label with the appropriate text. This minor label change is being made via notification because it does not affect the dosage, concentration, frequency or method of application or increase the amount of exposure. All changes have been highlighted on the first revised label included in this package.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If you have any questions regarding this submission, please contact me at 402-938-7079.

Sincerely,

Kelly R. Hoskins
Manager of Regulatory Affairs

Enclosures

Sergeant's Master Label

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Information in [] is optional.

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FRONT PANEL

CAT SPOT ON FIPRONIL

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels. The CRP required text will not change.]

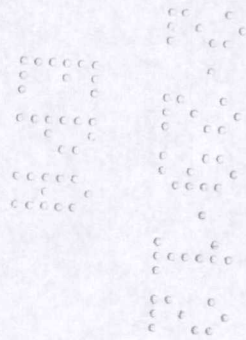
Sergeant's Fipronil Spot-On for Cats

NOTIFICATION

MAY 29 2012

[ABNs:]

- [(Sergeant's®) (Sentry®) Frontier Gold (Spot On) for cats]
- [(Sergeant's®) (Sentry®) Ectoadvance (Spot On) for cats]
- [(Sergeant's®) (Sentry®) Gold FrontSpot (Spot On) for cats]
- [SentryProline (Spot On) for cats]
- [[SENTRY®] FIPROGUARD™ for cats]
- [[Sergeant's] PRONYL OTC™ for cats]
- [[Sergeant's®][SENTRY®] AdvanSpot (Spot On) for cats]
- [FiproSpot (Topical) for Cats (and kittens)]
- [EctoSpot (Topical) for Cats (and kittens)]
- [Ectopronil (Topical) for Cats (and kittens)]
- [EctoAdvance (Topical) for Cats (and kittens)]
- [F-Pronil (Topical) for Cats (and kittens)]
- [Meridian Animal Health]



- [For use ONLY on cats [[&] [and] kittens] OF ALL WEIGHTS over 8 weeks of age]
- [For use ONLY on cats] [of ALL weights] [over 8 weeks of age]
- [Apply to kittens over 8 weeks old]
- [Apply to kittens 8 weeks or older]

[Mosquitoes]

[Kills mosquitoes within 24 hours for up to 14 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

- [Kills chewing lice]
- [Rapid elimination of chewing lice infestation]
- [Fast Action against chewing lice infestations]

[Adult Fleas]

- [Kills adult fleas [for up to six weeks]]
- [Kills Fleas [Up to 4 weeks] [1 month] [30 days]!]
- [If cat is a high risk for flea reinfestation apply once a month]
- [Kills fleas which may be a source of flea allergy dermatitis] [or flea bite anemia]

[Multiple Infestations]

- [Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old and older]
- [Kills fleas, ticks, [mosquitoes] [&] [and] chewing lice]
- [Kills fleas, ticks, chewing lice [&] [and] [mosquitoes]]
- [Monthly flea, tick, [mosquito] and chewing lice protection]
- [Four] [4] [Three] [3] Way [Action] [Effectiveness] [Control] [kills fleas, [mosquitoes,] ticks, and chewing lice]
- [[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]
- [[Four (4) Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]

Sergeant's Master Label

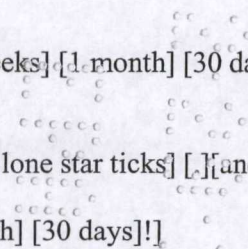
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[Once A Month Flea and Tick Treatment]
[Use **[Full or Partial Brand Name]** monthly to control ticks and chewing lice]
[Monthly flea, tick, [mosquito], and chewing lice protection.]
[Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]
[**[Full or Partial Brand Name]** provides convenient and effective flea, tick, chewing lice [and] [mosquito] control for cats and kittens over 8 weeks of age.]

[Ticks]

[Kills ticks including those that may transmit Lyme disease]
[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
[Kills deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]]
[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
[Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and lone star ticks] [,][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]]
[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!] 

[All Others]

[For Cats and Kittens 8 weeks of age or older]
[Can be used on kittens 8 weeks of age and older]
[Specially Formulated for Cats and Kittens Over 8 Weeks Old]
[Fast Acting] [Long Lasting]
[Easy to Use [Application]]
[Best if used year round!]
[Apply monthly]
[Once a month treatment]
[For year-round protection, apply **[Full or Partial Brand Name]** monthly]
[(ICON Showing [4 Week] [1 month] [30 day] Protection)]
[Apply once every [4 weeks] [month] [30 days]!]
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
[[One][1][Two][2][Three] [3][4][Four][5][Five] [Six][6][Twelve][12][Twenty-Four][24]]Applications and/or [1 Month Supply][2 Month Supply][3 Month Supply][Four Month Supply][Five Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][20 week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]
[Waterproof]
[Effective even after bathing]
[Effective after bathing and exposure to water and sunlight]
[Can be used on breeding, pregnant and lactating [queens], [female] [cats]]
[[Free] Calendar Stickers Inside!]
[Monthly application reminder inside]
[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][clip] [inside]]
[Fipronil (9.7%)]
[Contains Fipronil[,][-] the [same] active ingredient used in Frontline Top Spot® for cats*]
[***[Full or Partial Brand Name]** is not manufactured by or distributed by Merial. Frontline Top Spot® is a registered trademark of Merial.]
[[**[Full or Partial Brand Name]** is a trademark of [Company Name]]
[[1][2][3][4][5][6][12][24] applications]
[Stops and prevents infestation of listed pests for [4 weeks][1 month]]

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Sergeant's Master Label

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ACTIVE INGREDIENT:

Fipronil 9.70%

OTHER INGREDIENT:..... 90.30%

TOTAL **100.00%**

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See [Back][or][Side] [Label Panel[s]] for Additional Precautionary Statements

Net Contents: [1][One][2][Two][3] [Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.017 fl oz (0.50 mL) applicators

{END - FRONT PANEL}

BACK PANEL

**CAT SPOT ON
FIPRONIL**

[[Full or Partial Brand Name] contains Fipronil to effectively kill fleas and ticks [(including those that may transmit Lyme disease)]. [The active ingredients in [Full or Partial Brand Name] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for [1 month][4 weeks] on cats.]

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON CATS AND KITTENS OVER 8 WEEKS OF AGE**

[[Full or Partial Brand Name] provides [[four] [three] way] protection that kills fleas, ticks, [mosquitoes] and chewing lice. Kills deer ticks that may transmit Lyme disease. Kills brown dog ticks, American dog ticks, and lone star ticks. Prevents flea reinfestation for [[4][four] weeks] [[1] [one]month] [30 days].]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged cats. Call 1-800-781-4738 for 24-hour assistance.

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FIRST AID	
If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	

BACK PANEL

CAT SPOT ON FIPRONIL

DIRECTIONS FOR USE

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

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

Do not use on kittens under 8 weeks of age. Use entire contents of tube [vial] on each cat. [Do not split one tube between cats.] [Do not use multiple tubes on one cat.] Consult a veterinarian before using this product on debilitated, aged, or medicated cats. Can be used on breeding, pregnant, or lactating [cats] [female cats] [queens]. Consult a veterinarian before using on cats with known organ dysfunction. Cats may experience some temporary irritation at the site of product application. Certain medications can interact with pesticides. 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.

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



[{Outer Packaging}]

How to open: Remove product tubes [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

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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. [Studies show that] [Full or Partial Brand Name] kills adult fleas for up to six weeks. Apply monthly if your cat 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] [This product] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks]. [(Full or Partial Brand Name) can be used on breeding, pregnant and lactating (queens) (female cats).]

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.

BACK PANEL

CAT SPOT ON FIPRONIL

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.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] 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)

[Coupon(s) inside or on outside of box]
[Made in USA]

Distributed by:
Sergeant's Pet Care Products, Inc.
P.O. Box 540399
Omaha, NE 68154-0399
{END - BACK / SIDE PANEL}

[BAR CODE AREA][Lot code]
EPA Reg. No. 2517-137
EPA Est. No. 2517-TN-1 [XXX-XX-XXX]

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OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

CAT SPOT ON FIPRONIL

[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.]

[Application Instructions] [Directions for Use]

How to Open:

1. Remove product tubes [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] [to] 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 finished label]



[Look at the Label (Look at the Label icon) [Easy] 6 Step [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]

[3] [Month [Treatment] [Application] Tracker]

[For year round protection apply [Full or Partial Brand Name] monthly.]

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

[First][1st]Second][2nd]Third][3rd]Fourth][4th]Fifth][5th]Sixth][6th]Seventh][7th]Eighth][8th]Ninth][9th]Tenth][10th]Eleventh][11th]Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[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)]

[Monthly reminder card]

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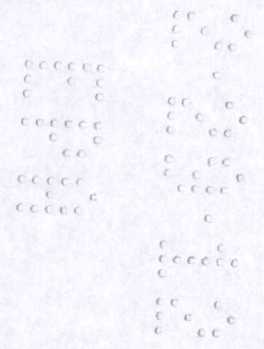
OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

CAT SPOT ON FIPRONIL

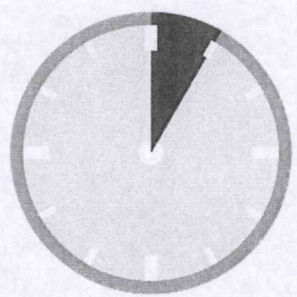
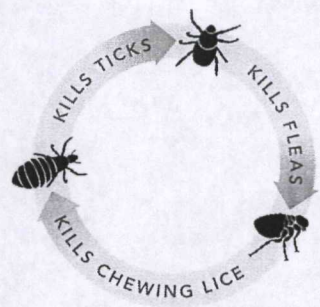
[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [**Full or Partial Brand Name**]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

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

- | | |
|--|--|
|  fleas |  fleas |
|  Adult Flea |  Adult Flea |
|  ticks |  ticks |
|  Deer Tick |  Deer Tick |
|  Brown Dog Tick |  Brown Dog Tick |
|  Lone Star Tick |  Lone Star Tick |
|  American Dog Tick |  American Dog Tick |
|  chewing lice |  chewing lice |
|  mosquitoes |  mosquitoes |



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



{END - OPTIONAL PACKAGE COPY}

TUBE/VIAL LABEL

CAT SPOT ON FIPRONIL

Front Label	Back Label
<p>{Brand Name} [For use only on cats/kittens 8 weeks or older] Fipronil 9.7% w/w 0.017 fl oz</p>	<p>KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open. EPA REG. No. 2517-137</p>
{label code}	{label code}

{END - TUBE/VIAL COPY}