

2517-80

12-6-2007

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DEC 6 2007

Ms. Karen E. Warkentien
Lewis and Harrison
Agent for Sergeant's Pet Care Products, Inc.
122 C street N.W., Suite 740
Washington, DC 20001

Dear Ms. Warkentien:

Subject: Amendment- data submitted as condition of notice of registration (MRIDs 47163701 and 47163702) to support spot-on against fleas, ticks and mosquitoes
Sergeant's Cypernothrin+ IGR Squeeze-On for Dogs
EPA Registration Number 2517-80
Your submission dated July 20, 2007

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

Based on the data submitted there are still outstanding data requirements for the efficacy of cypermethrin against mosquitoes, the efficacy and duration of effectiveness of s-Methoprene as a flea ovisterilant, and the length of effectiveness of pyriproxyfen (Nylar) against flea egg and larvae. The data provided in the submission fail to satisfy these requirements. Therefore, you must submit the requested data or remove the unsupported claims. We note you have committed to satisfy these data requirements and provide said data within the constraints imposed in the original notice of registration. With respect to the labeling we have the following comments:

- a) All label claims regarding effectiveness up to 8 weeks/2 months (e.g., works, kills, repels, prevents, x week/y month dose) must be specific to adult fleas and ticks only. Also, Kills [flea eggs] for up to [24 days][4 weeks][1 month] is acceptable.
- b) Claims against mosquitoes must be explicitly stated as "for up to 28 days/4 weeks/1 month".
- c) Remove the following marketing statements:
 - (1) [• [Five] [5] Way Protection [Kills fleas, ticks, mosquitoes, flea eggs & flea larvae]]*
 - (2) [• Five Way Protection! Kills ticks, mosquitoes fleas, flea eggs & flea larvae]*
 - (3) [• 5 Way Protection! Kills ticks, mosquitoes, fleas, flea eggs & flea larvae]*
 - (4) [(ICON Showing [4] [5] [6] [7] [8] Week Protection)]
 - (5) [Fast Acting]
 - (6) [Kills [and Repels 100% of [fleas] [and] [ticks] in as little as 1 hour]
 - (7) [Kills [and repels] 93-100% of [fleas] [and] [ticks] for up to 8 weeks]

- (8) [Kills [and repels] 96.5% - 100% of [fleas] [and] [ticks] for up to 7 weeks]
- (9) [Kills [and repels] 98%-100% of [fleas] [and] [ticks] for [5] [6] weeks]
- (10) [Kills [and repels] up to 100% of [fleas] [and] ticks] for up to [30 days [1 month] [4 weeks] [5 weeks] [6 weeks] [7 weeks] [8 weeks] [2 months]
- (11) [Nothing works faster, Nothing lasts longer]
- (12) [100% Guaranteed!]
- (13) [Outlasts, Outperforms, Outprotects]
- (14) [Speed-of-kill that lasts]

d) Revise the following statements as indicated:

- (1) [Sergeant's Squeeze-On Flea & Tick Control with methoprene is an effective and easy to use product.] [Sergeant's Squeeze-On Flea & Tick Control with methoprene prevents eggs from fleas on treated dogs from developing into biting adults for up to 30 days.] [As with all flea and tick control products, Sergeant's Squeeze-On Flea and Tick Control with methoprene should be used as part of a program aimed at reducing flea populations in the dog's environment (bedding, carpets, kennel, yard).] [Consult your retailer for program recommendations.]
- (2) Up to [• [Four [4] [5] [6] [7] [8] Week] [Flea and Tick Control]]*
- (3) Up to [•[4] [5] [6] [7] [8] Week Protection against fleas and ticks!]
- (4) Up to [• [4] [5] [6] [7] [8] week][[1][2]month] Flea and Tick Treatment!]*
- (5) [• Kills [& Repels] [for up to [4] [5] [6] [7] [8] Weeks] Fleas [in as little as 1 hour], and ticks [in as little as [4][3] hour[s]] [for up to [4] [5] [6] [7] [8] weeks]]
- (6) Up to [[4] [5] [6] [7] [8] week dose]
- (7) [Frequency of Application: When used monthly, the product ~~completely~~ breaks the flea life cycle and controls flea, tick and mosquito infestations. Research demonstrates that [product brand name] kills adult fleas and ticks for up to 8 weeks, and also prevents development of all flea egg and larval stages for up to four weeks. A once monthly application is recommended where mosquito control is needed.]

e) On page 3 under Net Contents delete "Apply Once Every Month" this statement is in conflict with claims of more than 4 week control that is claimed on this label.

f) The ingredient statement must be on the front panel of the label. Marketing claims and graphics on the front panel is not justification for placing the ingredient statement on the back/side panel.

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A copy of the efficacy review is enclosed for your records.

A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please contact Linda A. DeLuise of my team at (703) 305-5428.

Sincerely,

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505P)

Enclosure

[CARTON LABEL - DRAFT MASTER LABEL COPY]

Sergeant's Cyphenothrin+IGR Squeeze-On for Dogs
[(ABN) Sergeant's Gold Flea and Tick Squeeze-On for Dogs]
[(ABN) Sergeant's Gold Squeeze-On for Dogs]
[(ABN SentryPro XFC[Extreme Flea Control] Squeeze-On for Dogs]
[(ABN) SentryPro XFC[Extreme Flea Control] Flea and Tick Squeeze-On for Dogs]

• **DO NOT USE ON CATS [Box/Icon with Cat Image and Cross-Out]**

- [• Flea & Tick Control for Dogs & Puppies 12 weeks old and older]
- [• [12],[15],[18], [21][24] [32] [52] Week Supply For Dogs weighing [more than 9 lbs],[9 to 20 lbs], [21 to 39 lbs] [40 to 60 lbs] [61 lbs and over]*
- [Works up to [4] [four] [5] [6] [7] [8] Weeks!]
- [Protects for up to [4] [Four] [6] [7] [8] Weeks!]
- [Kills fleas, ticks, mosquitoes, flea eggs, and flea larvae]
- [• [Five] [5] Way Protection [Kills fleas, ticks, mosquitoes, flea eggs & flea larvae]]*
- [• Five Way Protection! Kills ticks, mosquitoes fleas, flea eggs & flea larvae]*
- [• 5 Way Protection! Kills ticks, mosquitoes, fleas, flea eggs & flea larvae]*
- [• [4] [5][6] [7] [8] Week [Flea & Tick Treatment]*
- [•) [4] [5][6] [7] [8] Week [Flea and Tick Control]*
- [• With Nylar® Insect Growth Regulator which Breaks the Flea Life Cycle]*
- [• With Nylar® to Break Flea Life Cycle]*
- [• With Insect Growth Regulator to Break Flea Life Cycle]*
- [• Dual Action [!]: Cyphenothrin with Nylar® IGR Effectively Breaks the Flea Life Cycle]*
- [• Dual Action [!]: Effectively Breaks the Flea Life Cycle[!]]*
- [• For Dogs & Puppies (Over 12 Weeks of Age) and greater than 9 lbs.]
- [• For Dogs & Puppies (Over 12 Weeks of Age) 9 to 20 lbs.]
- [• For Dogs & Puppies (Over 12 Weeks of Age) 21 to 39 lbs.]
- [• For Dogs & Puppies (Over 12 Weeks of Age) 40 to 60 lbs.]
- [• For Dogs & Puppies (Over 12 Weeks of Age) 61 lbs and Over]
- [• Three Applications {for cartons with 3 applicators}] and/or [3 Month Supply] or [12 Week Supply]
- [• For Dogs [more than 9 lbs.] or [9 lbs. to 20 lbs.] or [21 lbs. to 39 lbs.] or [40 lbs. to 60 lbs.] or [61 lbs. and Over]]
- [• Breaks Flea Life Cycle!]*for up to 9 weeks]
- [Controls reinfestation for up to 9 weeks!]
- [• Best if used year round!]
- [• Kills & Repels Fleas Up to [4 weeks]!]* [5 weeks] [6 weks] [7 weeks] [8 weeks]
- Kills [& Repels] fleas in as little as 1 hour!
- Kills [& Repels] ticks in as little as [1] [3] hours!

ACCEPTED
with COMMENTS
by EPA Review Board

DEC - 6 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

2517-80

- [Kills fleas and ticks] [in as little as 1 hour], [mosquitoes], [flea eggs & flea larvae]
- Kills [and Repels] 100% of [fleas] [and] [ticks] on Day 30
- Long Lasting
- Fast Acting
- Kills [and Repels] 100% of [fleas] [and] [ticks] in as little as 1 hour
- Kills[and repels] 93-100% of [fleas] [and] [ticks] for up to 8 weeks
- Kills [and repels] 96.5%-100% of [fleas] [and] [ticks] for up to 7 weeks
- Kills [and repels] 98-100% of [fleas] [and] [ticks] for [5] [6] weeks
- Kills [and repels] up to 100% [fleas] [and ticks] for up to [30 days] [1 month] [4weeks] [5 weeks] [6 weeks] [7 weeks] [8 weeks] [2 months]

- [Kills [and Repels]
 - Fleas [in as little as 1 hour]
 - Ticks [in as little as [1] [3] hours]
 - [Mosquitoes]
- [Kills for [9 weeks] [63 days]]
 - [flea eggs]
 - [flea larvae]
- [(ICON Showing [4] [5] [6] [7] [8] Week Protection)]
- [4 Week Dose!][5 week] [6week] [7 week] [8 week] Dose!
- [1 Month Dose!] [2 month dose]
- [Prevents ticks from attaching and feeding in as little as [1 hours] after application]
- [Kills and Detaches Ticks]
- [Easy to Use Application]
- [Specially Formulated for Dogs and Puppies]
- [4] [5] [6] [7] [8]Week flea and tick Protection!]
- [[Free] Calendar Stickers Inside!]
- [[Free] Brochure Inside!]
- [[Free] Brochure and Calendar Stickers Inside]
- [Patented Technology] [Patent pending technology]
- [• Kills Flea Eggs & Flea Larvae for more than [63 days], [9 weeks]!]*
- [• Prevents Flea Eggs From Developing Into Biting Adults]*
- [• Kills & Repels Ticks for Up to [4] [5] [6] [7] [8] weeks]!]*
- [• Kills & Repels Deer Ticks (vector of Lyme Disease) for up to [4] [5] [6] [7] [8] weeks]
- [• Kills & Repels Ticks (Including Deer Ticks) for up to 4 weeks]
- [• Kills & Repels Brown Dog Ticks [(*Rhipicephalus sanguineus*)] for up to [4] [5] [6] [7] [8]weeks!]

[CARTON LABEL - MASTER LABEL COPY]

- [• Kills & Repels American Dog Ticks [(*Dermacentor variabilis*)] for up to [4] [5] [6] [7] [8] weeks!]
- [• Apply once every [4] weeks] [month]!]
- [• [4] [5] [6] [7] [8] week Flea and Tick Treatment!]
- [One] [2] Month Flea and Tick Treatment]

- [• Kills & Repels Fleas and Ticks for up to [4] [5] [6] [7] [8] weeks!]
- [• Kills all stages of the flea life cycle]
- [• Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to [4 Weeks] [1 month]
- [Kills [and Repels] mosquitoes]

[Nothing works faster, Nothing lasts longer]
 [100% Guaranteed!]
 [Outlasts, Outperforms, Outprotects]
 [Speed-of-kill that lasts!]

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

[] - Denotes Optional Statements and/or Images that May be Used on Front, Back or Side Label Panels

***Note: Underscored Claims To Be Based on New as well as Existing Product Performance (Efficacy) Data**

[Ingredient Statement may be on front or back label]

ACTIVE INGREDIENTS:

Cyphenothrin (CAS# 39515-40-7) 40.0%
 Pyriproxyfen (CAS# 95737-68-1) 2.0%

OTHER INGREDIENTS: 58.0%

TOTAL: 100.0%

Nylar® is a registered trademark of McLaughlin Gormley King Company.
 U.S. Patent No. 5,942,525

**KEEP OUT OF REACH OF CHILDREN
 CAUTION**

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

NET CONTENTS: [THREE] [FOUR] [SIX][TWELVE] 1.5 ml Tubes
[THREE][FOUR][SIX][TWELVE] 3.0 ml Tubes
[THREE][FOUR][SIX][TWELVE] 4.5 ml Tubes
[THREE][FOUR][SIX][TWELVE] 6.0 ml Tubes

[BACK/SIDE CARTON LABEL - MASTER LABEL]
[Apply Once Every Month]

7 8 10

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES OVER 12 WEEKS OF AGE.
DO NOT USE ON CATS**

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

FIRST AID	
If in eyes	<ul style="list-style-type: none">• 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 or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give any liquid to the person.• Do not give anything by mouth to an unconscious person.
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.	
NOTE TO PHYSICIAN OR VETERINARIAN Treat patient symptomatically	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **DO NOT USE ON CATS.** May be toxic and potentially fatal if applied to or ingested by cats.

FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 12 weeks of age. Best if used year round. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. **DO NOT USE ON CATS** or animals other than dogs. Cats that actively groom or engage in close physical contact with treated dogs may be at risk of serious harmful effects. Sensitivities may occur after using ANY pesticide product on pets. If signs of sensitivity occur bathe your dog with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

How to apply: Remove product tube from package. Holding tube with top end pointing up and away from face and body, [snap or] cut off top end. Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Repeat application may be made if necessary, but do not apply more often than once every 4 weeks.

[Frequency of Application:

When used monthly, product completely breaks the flea life cycle and controls flea, tick and mosquito infestations. Research demonstrates that [product brand name] kills adult fleas and ticks for up to 8 weeks, also prevents development of all flea stages for up to nine weeks. A once monthly application is recommended where mosquito control is needed.]

[BACK/SIDE CARTON LABEL - MASTER LABEL]

For Dogs Weighing Between 9 and 20 lbs.: {For cartons containing 1.5 ml (0.05 fl. oz.) applicator tubes}

Apply one tube (1.5 ml)(0.05 fl. oz.) [as a spot to the dog's back between the shoulder blades]or [from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing Between 21 and 39 lbs. {For cartons containing at least two 1.5 ml (0.05 fl. oz.) applicator tubes, or at least one 3.0 ml (0.10 fl. oz.) applicator tube}

[Apply two tubes (1.5 ml)(0.05 fl. oz.) as a spot on the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

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[For cartons containing one 3.0 ml (0.10 fl. oz) applicator tube] [Apply one tube (3.0 ml)(0.10 fl. oz.) as a spot or stripe to the dog's back between the shoulder blades.] or [from the back of the neck to a point midway between the neck and tail.

For Dogs Weighing Between 40 and 60 lbs. [For cartons containing at least three 1.5 ml (0.05 fl. oz.) applicator tubes], e}

[Apply two tubes (1.5 ml)(0.05 fl. oz.) as a spot or stripe to the dog's back between the shoulder blades and apply the third tube from the back of the neck to a point midway between the neck and tail]. [For cartons containing one tube (4.5ml) (0.15 fl.oz.)] [Apply one tube (4.5 ml)(0.15 fl. oz.) from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing 61 lbs. and Over: [For cartons containing at least four 1.5 ml (0.05 fl..oz.) applicator tubes] [Apply two tubes (1.5 ml) (0.05 fl. oz.) as a spot or stripe to the dog's back between the shoulder blades and apply the contents of the othe two tubes (1.5 ml) (0.05 fl. oz.) from the back of the neck to a point midway between the neck and tail.] or [For cartons containing at least two 3.0ml (0.10fl. oz.) applicator tubes]

[Apply one tube (3.0 ml)(0.10 fl. oz.) as a spot to the dog's back between the shoulder blades and apply the contents of the other tube (3.0 ml each)(0.10 fl. oz.) from the back of the neck to a point midway between the neck and tail.] [For cartons containing one tube (6.0 ml) (0.20 fl. oz.)] - or - [Apply one tube (6.0 ml)(0.20 fl. oz.) from the back of the neck to a point midway between the neck and tail.]

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 25⁰C) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

DISPOSAL: If empty: Do not reuse this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. **Never place unused product down any indoor or outdoor drain.**

[Sergeant's Squeeze-On Flea & Tick Control with Nylar® Insect Growth Regulator is an effective and easy to use product.] [Sergeant's Squeeze-On Flea & Tick Control with Nylar® Insect Growth Regulator prevents eggs from fleas on treated dogs from developing into biting adults for 63 days.] [7 weeks][As with all flea and tick control products, [Sergeant's Squeeze-On Flea and Tick Control with Nylar® Insect Growth Regulator] should be used as part of a program aimed at reducing flea populations in the dog's environment (bedding, carpets, kennel, yard).] [Consult your retailer for program recommendations.]

Visit us at www.sergeants.com

MADE IN USA

Sergeant's is committed to providing high quality products. If you have questions or comments about this product, please write: Sergeant's Consumer Response; P.O. Box 540399; Omaha, NE 68154-0399.

[Satisfaction Guaranteed!] [Please return for a refund if not completely satisfied!]

In Case of Emergency, call 1-800-781-4738
Non-emergency: call 1-800-224-PETS(7387).

[WARRANTY: SERGEANT'S PET CARE, INC. MAKES NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR OTHERWISE, EXPRESSED OR IMPLIED, CONCERNING THIS PRODUCT OR ITS USES WHICH EXTEND BEYOND THE USE OF THE PRODUCT UNDER NORMAL CONDITIONS IN ACCORDANCE WITH THE STATEMENTS MADE ON THIS LABEL.]

[Made in the USA For:] or [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68130
EPA Reg. No. 2517 -80
EPA Est. No. 2517-TN-1

[BAR CODE AREA]

[TUBE/APPLICATOR LABEL]

FRONT PANEL -

Sergeant's Squeeze-On Flea & Tick Control with Nylar® Insect Growth Regulator, [Box/Icon with Cat Image and Cross-Out], [1.5 ml] or [3.0 ml] or [4.5 ml] or [6.0 ml], Cyphenothrin 40.0% W/W, Pyriproxyfen 2.0% W/W

BACK PANEL -

READ DIRECTIONS/PRECAUTIONS BEFORE USING.
CAUTION: KEEP OUT OF REACH OF CHILDREN
EPA REG. NO. 2517-80