09 05 2013



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 05, 2013

Mr. James Messina Authorized Representative of Sergeant's Pet Care Product, Inc. c/o Exponent 1150 Connecticut Ave. NW, Suite 1100 Washington, DC 20036

Subject:

Application for Pesticide Amendment Cyphenothrin + Pyriproxyfen Squeeze-On for Dogs (30%) EPA Reg. No. 2517-130 Your Submission Dated February 26, 2013 Decision No: 480592

Dear Mr. Messina:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

#### **Conditions of acceptance**

- 1. This registration is now time-limited and expires two years from the date of this letter.
- 2. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future and no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
- 3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, 2014. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the attention of Kaitlin Keller, Pesticide Reevaluation Division, Mail Code 7508P.

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number Product name (brand name) Lot # Where purchased: internet, store, veterinarian Active Ingredient(s) Weight range for product

Date on which incident occurred. (mm/dd/yyyy) State in which the incident occurred. (standard 2 letter abbreviation) Registrant case #

Species: dog, cat, other (specify) Breed: (as reported by pet owner) Age: months or years Sex: M, F, or neutered Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted with separate column for each sign, using standard terminology Time to Onset: (hours, days) Treated by veterinarian: yes or no First time product used: yes or no Misuse: use on incorrect species, overdose, too frequent dosing, other (describe) Any known precondition EPA Severity Code: death, major, moderate, minor Outcome: died, recovered, still treated, unknown

- 4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
  - All incidents should be reported including all minor dermal and ocular irritation reports.
  - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all spot-on products, the Agency will inform registrants and if needed, EPA may take regulatory action. If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at: Benmhend.driss@epa.gov.

Sincerely,

Mark Suárez Product Manager 13, Insecticide Branch Registration Division (7504P)

Enclosure: Label stamped "Accepted"

	Sergeant's Master	Laber
2 Sep 2013 Amendment	v13.1	EPA No. 2517-130
nformation in [] is optional. RONT PANEL	Page 1 of 8	EPA SAL 09 Oct 2012 PHENOTHRIN & PYRIPROXYFEN
		all of the optional text on front, back or side
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Multiple species]		
	ea larvae][Repels mosquitoes]	4 ] .
, 10	gs, flea larvae] [Repels mosqui	-
	Kills ticks, fleas, flea eggs & fle	
		, and ticks, and repels mosquitoes]]
	fleas, flea eggs, flea larvae, and	ticks, and repels mosquitoes]]
Kills all stages of the flea life	÷ –	
	nd flea larvae [and repels mosq	
	vae, ticks, and repels mosquitoe	-
—	ourj, [and] [ticks] [in as little as	3 hours], [flea eggs & flea larvae] [and
epels mosquitoes]]	ourl [and] Ticks [in as little as 2	hours
	our] [and] Ticks [in as little as 3	
Works for up to 4 Weeks on :		equitoes] for up to [4 Weeks] [1 month]]
Protects for up to 4 Weeks on Protects for up to 4 Weeks or	-	
	Adult] Flea and Tick [Control]	[Protection!] [Treatment!]]
Kills [Adult] Fleas and Ticks		
	n [less than][just] [5][15] minu	tes] [after application]
	i [just] [5][15] minutes] [after a	
Stops][Prevents] fleas [from		r r]
Kills fleas before they bite	-01[	
	han] [just] 1 hour [after applica	tion]].
	n [less than] [just] [1 hour] and	
		ticks in [as quick as] [just] 3 hours [after
pplication]]		
Kills Fleas, Ticks] [Kills Flea	a Eggs, Flea larvae][Repels mos	squitoes]
Flea and Flea eggs and Lar	vall	
	m][just] [5][15] minutes] [after	application]
	n] [just] [5][15] minutes] [after	
Kills fleas in 1 hour] [after ap		approation]
	iting][before they bite][dogs][y	our dog]
Stops][Prevents] fleas from in		
Stops fleas from biting [which		
1 01	h may cause [flea allergy] derm	atitisl
	y cause flea allergy dermatitis]	
Stops][Kills] fleas which ma		
Kills fleas before they [can] b		
Quickly kills fleas in [less that	-	
With Pyriproxyfen to Break I		
With Insect Growth Regulato		
-	rowth Regulator which Breaks	the Flea Life Cycle]
	Breaks the Flea Life Cycle [!]]	L 2
	•	ectively Breaks the Flea Life Cycle]
Prevents Flea Eggs From Dev		· · · · · · · · · · · · · · · · · · ·
Breaks Flea Life Cycle!] for		
Controls reinfestation for up		
-		
Kills Flea Eggs & Flea Larva	e for up to [63 days], [9 weeks]	[ <b>!</b> ]

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[Kills fleas in as little as 1 hour!] [Kills Fleas for up to 4 weeks!] [Kills Adult Fleas for up to 4 weeks!]

### [Ticks]

[Starts killing ticks in [less than][just] [5][15] minutes] [after application]
[Starts to kill ticks in [just] [5][15] minutes] [after application]
[Kills ticks in 3 hours] [after application]
[Quickly kills ticks in [as little as] [just] 3 hours][!]
[Kills and Detaches Ticks]
[Kills ticks in [as little as] [just] 3 hours][!]
[Prevents ticks from attaching and feeding [in as little as] [3 hours]]
[Kills ticks including those that may transmit Lyme disease]
[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
[Kills deer ticks [before they can] [that] [transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days]]]
[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
[Kills Ticks (Including 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]!]

### [Mosquitoes]

[Repels mosquitoes]

[Repels mosquitoes within 24 hours]

[Repels mosquitoes] [for up to [30 days] [4 weeks] [1 month] !]

[Repels mosquitoes that may transmit heartworm]

[Repels mosquitoes that may transmit [heartworm] [West Nile virus] [from feeding on dogs] [for up to [one month] [30 days][ 4 weeks]]

[Repels Mosquitoes] [Prevents mosquitoes that transmit West Nile virus and heartworm] [from feeding on dogs] [for up to [one month] [30 days][ 4 weeks]]

[Prevents mosquitoes from blood feeding, which may transmit viruses such as West Nile Virus and heartworm to dogs for up to four weeks.]

#### **ACTIVE INGREDIENTS:**

Cyphenothrin (CAS# 39515-40-7)	
Pyriproxyfen (CAS# 95737-68-1)	2.00%
OTHER INGREDIENTS[*]:	
TOTAL	100.00%]
[*(Diethylene glycol monoethyl ether, vitamin E nicotinate)]	

KEEP OUT OF REACH OF CHILDREN CAUTION

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

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NET CONTENTS: XXX fl oz (XXX mL)

[THREE][FOUR][SIX][TWELVE]

[0.05 fl oz (1.5 mL) Tubes] [0.10 fl oz (3.0 mL) Tubes] [0.20 fl oz (6.0 mL) Tubes]

# {END – FRONT PANEL}

### BACK/SIDE PANEL DOG SQUEEZE ON CYPHENOTHRIN & PYRIPROXYFEN

### [Apply Once Every Month] [Can be applied monthly [if needed]]

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

## PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS. CAUTION:** Causes moderate eye irritation. Avoid contact with eyes or clothing. Harmful if swallowed or absorbed through skin. Wash 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 on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

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> </ul>			
<ul> <li>Call a poison control center or doctor for further treatment advice.</li> <li>IF ON SKIN</li> <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 SWALLOW ED	<ul> <li>Call a poison control center or doctor for treatment advice.</li> <li>Immediately call a poison control center or doctor.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> </ul>			
<ul> <li>Have person sip a glass of water if able to do so.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>				
HOT LINE NUMBER				
going for treatr	ict container or label with you when calling a poison control center or doctor, or nent. For more information on this pesticide product (including health concerns, encies or pesticide incidents), you may call 1-800-781-4738.			
	<b>NOTE TO PHYSICIAN OR VETERINARIAN</b> Treat patient symptomatically			

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#### **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 DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats or animals other than dogs. Do not allow your dog to ingest this product. Do not use on dogs less than 61 lbs. Use entire contents of tube vial on each dog. [Do not split one tube between dogs.] [Do not use multiple tubes on one dog.] Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

[1.5cm x 1.5cm on final or as indicated]

DO NOT USE ON CATS. MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

#### {Outer Packaging}

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

[Optional drawings that may or may not appear anywhere on finished label]



#### **Frequency of Application:**

[When used monthly, {**product name**} breaks the flea life cycle and controls flea and tick infestations.]

#### **Only For Dogs Weighing 61 lbs and Over:**

#### {For cartons containing four 1.5 mL (0.05 fl oz) applicator tubs}

[Apply two tubes (1.5 mL) (0.05 fl oz) as a spot or stripe to the dog's back between the shoulder blades

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and apply the contents of the other 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 two 3.0 mL (0.10 fl 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.].

### OR

## {For cartons containing one 6.0 mL (0.20 fl oz) applicator tubes}

[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.]

Do not apply to dogs weighing less than 61 lbs.

### 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 out of reach of children. Do not refrigerate. Protect from direct sunlight.

**PESTICIDE DISPOSAL AND CONTAINER HANDLING**: Nonrefillable container. Do not reuse or refill this container. **If empty**: Place in trash or 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.

[Brand name] is an effective and easy to use product.] [Brand name] prevents eggs from fleas on treated dogs from developing into biting adults for up to 63 days] [9 weeks]. [As with all flea and tick control products, [Brand name] 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.]

## [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.]

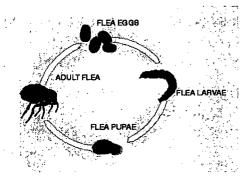
[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399]

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][Manufactured in USA]

S	ergeant's Ma	ster Label	
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Information in [] is optional.	Page 7 of 8	EPA SAL 09 Oct 2012	
Made in the USA For:] or [Manu	factured by:][Distribut	ted by:]	
Sergeant's Pet Care Products, Inc	<b>C.</b> :	EPA Reg. No. 2517-130	
Omaha, NE 68138-3710		EPA Est. No. XXXXX-XX-XX	
<i>`</i>		[lot, date & label code] [UPC CODE]	

### {END - BACK / SIDE PANEL} OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGING DOG SQUEEZE ON Cyphenothrin & Pyriproxyfen

[Optional drawings and information that may or may not appear anywhere on finished label]



(Insert diagram that includes checklist with magnifying glass and checklist graphic)

[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 dog
- [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][application] for at least 24 hours to avoid chance of ingestion
- [6] Do NOT split tubes between dogs [and use the ENTIRE tube contents.]]

#### [Brand Name]

[1][2][3][4][5][6][12][24][Month [Application] Tracker]
[For year-round protection, apply [Brand Name] monthly.]
[Dog's Name (Empty blank for owner to fill in name)]
[First][1st][Second][2nd][Third][3rd][Fourth][4<sup>th</sup>][Fifth][5<sup>th</sup>][Sixth][6<sup>th</sup>][Seventh][7<sup>th</sup>][Eighth][8<sup>th</sup>][Nin th][9<sup>th</sup>][Tenth][10<sup>th</sup>][Eleventh][11<sup>th</sup>][Twelfth][12<sup>th</sup>]
[Dose] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)]
[calendar stickers with [Brand Name]
[Place stickers on your calendar as a reminder to reapply [Brand Name] [in 30 days.]

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

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Information in [] is optional.	Page 8 of 8	EPA SAL 09 Oct 2012	

[How to apply: 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.]

# [Only For Dogs Weighing 61 lbs and Over:

## {For cartons containing four 1.5 mL (0.05 fl oz) applicator tubs}

[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 other 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 two 3.0 mL (0.10 fl 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.]

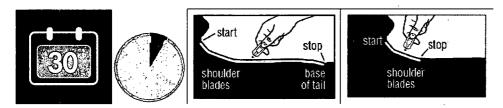
## OR

## {For cartons containing one 6.0 mL (0.20 fl oz) applicator tubes}

[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.]

Do not apply to dogs weighing less than 61 lbs.

[Optional graphic that may or may not appear anywhere on finished label]



# {END - BACK / SIDE PANEL}

# TUBE / VIAL LABEL DOG SQUEEZE ON CYPHENOTHRIN & PYRIPROXYFEN

## **Front Label**



KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open.

EPA REG. No. 2517-130

Back Label

{label code}

{Brand Name} For Dogs [61 lbs. and over] [more than 61 lbs.]  $\geq$  12 wks Cyphenothrin 30.00%, Pyriproxyfen 2.00% 0.05 fl oz (or) 0.10 fl oz (or) 0.20 fl oz {label code} {END - TUBE/VIAL COPY}