

2517-140

02-21-2012

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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 Squeeze-On for Dogs
EPA Reg. No. 2517-136
- Sergeant's Fipronil + Methoprene Squeeze-On for Dogs
EPA Reg. No. 2517-134
- Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs
EPA Reg. No. 2517-140
- Sergeant's Fipronil + Nylar Squeeze-On for Dogs
EPA Reg. No. 2517-141
- Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs EPA
Reg. No. 25 17-142
- Sergeant's Fipronil + Cyphenothrin + NyJar Squeeze-On for Dogs
EPA Reg. No. 2517-143

Applications dated September 26, 2011

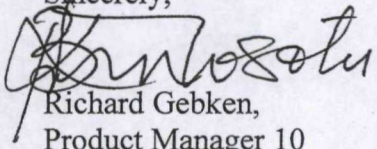
Dear Mr. Messina:

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*

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

Sergeant's[®] Master Label

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Information in [] is optional.

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FRONT PANEL

**DOG SQUEEZE ON
FIPRONIL+CYPHENOTHRIN**

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

Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs

- [ABNs][Sergeant's[®] (Sentry[®]) EctoAdvance™ (Spot On) for dogs]
- [ABNs][Sergeant's[®] (Sentry[®]) FiproGuard™ (Spot On) for dogs]
- [ABNs][Sergeant's[®] (Sentry[®]) FiproGuard™ Max (Spot On) for dogs]
- [ABNs][Sergeant's[®] (Sentry[®]) Pronyl OTC™ Max (Spot On) for dogs]
- [ABNs][Sergeant's[®] (Sentry[®]) AdvanSpot Plus (Spot On) for dogs]

- [Apply to puppies over 12 weeks old]
- [Apply to puppies 12 weeks or older]

[Mosquitoes]

- [[Kills mosquitoes] [within 24 hours for up to the first 7 days after application, and within 48 hours for up to 28 days]
- [Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]
- [Kills mosquitoes]

[Chewing Lice]

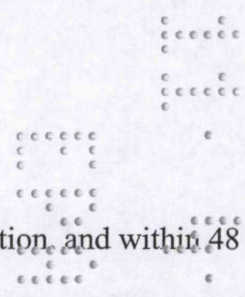
- [Kills chewing lice]
- [Rapidly eliminates infestations of chewing lice]

[Fleas]

- [[Kills adult fleas (starts killing in as little as 1 hour) [for up to 3 months]]
- [Kills newly emerged adult fleas (starts killing in as little as 1 hour) before they lay eggs]
- [Kills fleas, which may be a source of flea allergy dermatitis] [or flea bite anemia]]
- [Kills fleas (starts killing in as little as 1 hour)]
- [Kills fleas (starts killing in as little as 1 hour) Up to [4 weeks] [1 month] [30 days]!]
- [If dog is at high risk of flea reinfestation apply once a month]

[Multiple Infestations]

- [Kills chewing lice and controls mites that may cause sarcoptic mange]
- [Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 12 weeks old [&] [and] older]
- [Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], [and] Chewing lice [&] [and] [Mosquitoes]]
- [Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], [and] kills Mosquitoes, [and] kills chewing lice]]
- [Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], and kills chewing lice [&] [and] [mosquitoes]]
- [Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], [mosquitoes,] and chewing lice]]
- [Monthly flea, tick, [mosquitoes,] and chewing lice application]



ACCEPTED
FEB 21 2012

**Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:**

EPA Reg. No. 2517-140

Sergeant's[®] Master Label

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL+CYPHENOTHIN

[[4 Week] [1 month] [30 day] [Flea and Tick Application]
[[Four (4) Week] [1 month] [30 day] [Flea, Tick, [Mosquitoes,] and Chewing Lice Application]
[Kills Fleas (starts killing in as little as 1 hour) and Ticks (starts killing in as little as 1 hour) for
up to [4 weeks] [1 month] [30 days]!]
[Once A Month Flea and Tick Application]
[Use [**Full or Partial Brand Name**] monthly to control Ticks (starts killing in as little as 1 hour)
and chewing lice]
[Monthly flea, tick, [mosquitoes,] and chewing lice protection.]
[Starts killing [fleas] [and] [ticks] in as little as 1 hour] [and continues to kill for a month] !]
[Flea & Tick Control for Dogs & Puppies 12 weeks old and older]

[Ticks]

[Kills Ticks (starts killing in as little as 1 hour) including those that may transmit Lyme disease]
[Kills ticks (starts killing in as little as 1 hour) for Up to [4 weeks] [1 month] [30 days]!]
[Kills] Deer Ticks [that may transmit Lyme disease,] for up to [4 weeks] [1 month] [30 days]]
[Kills Ticks (starts killing in as little as 1 hour)]
[Kills Deer Ticks for up to [4 weeks] [1 month] [30 days]!]
[Kills [Brown Dog Ticks] [(*Rhipicephalus sanguineus*), [American Dog Ticks,] [and Lone Star
Ticks] (in as little as 1 hour) [and deer ticks] for up to [4 weeks] [1 month] [30 days]]
[Kills [Brown Dog Ticks], [(*Rhipicephalus sanguineus*)] (starts killing in as little as 1 hour)
for up to [4 weeks] [1 month] [30 days]]
[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]
[Prevents and controls reinfestation of listed pests for [30 days][1 month]]
[Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever,
ehrlichiosis, babesiosis, and anaplasmosis]

[All Others]

[For Dogs and Puppies 12 weeks of age or older]
[Controls mites that may cause sarcoptic mange]
[For Dogs [up to 22 lbs], [23-44 lbs], [45-88 lbs], [89-132 lbs]]
[Fast Acting] [Long Lasting]
[Remains effective, even after bathing, water immersion, or exposure to sunlight]
[Easy to Use [Application]]
[One Application][Two Applications][Three Applications][Four Applications][Five
Applications][Six Applications][Twelve Applications][Twenty-Four Applications] and/or [1
Month Supply][Two 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]
[Best if used year round!]
[(ICON Showing [4 week] [1 month] [30 day] Protection)]
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
[Specially Formulated for Dogs and Puppies 12 weeks of age or older]
[[Free] Calendar Stickers Inside!]
[Monthly application reminder card inside]

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[Apply once every [4 weeks] [month] [30 days]!]

[Waterproof]

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL+CYPHENOTHRIN

[Can be used on puppies 12 weeks of age and older]

[[Convenient spot application][Convenient][to use]]

[Fipronil (9.8%) + Cyphenothrin (5.2%)]

[Lift [here] for more information]

[For year-round protection, apply [**Full or Partial Brand Name**] monthly]

[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][inside]]

[[1][2][3][4][5][6][12][24] Applications]

[Full or Partial Brand Name] is a trademark of [Company Name]

[For use ONLY on dogs [&] [and] puppies] [For Dogs & Puppies 12 weeks or older and]

[Up to 22 lbs]

[up to 22 lbs.]

[23[-] [to] 44 lbs]

[For Dogs 23[-] [to] 44 lbs.]

[45[-] [to] 88 lbs]

[For Dogs 45[-] [to] 88 lbs.]

[89[-] [to] 132 lbs]

[For Dogs 89[-] [to] 132 lbs.]

[over 12 weeks of age]]

ACTIVE INGREDIENTS:

Fipronil9.80%

Cyphenothrin5.20%

OTHER INGREDIENTS[*]:85.00%

TOTAL **100.00%**

[*Diethylene glycol monoethyl ether, Vitamin E nicotinate]

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] 0.023 fl oz (0.67 mL) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.045 fl oz (1.34 mL) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.091 fl oz (2.68 mL) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.136 fl oz (4.02 mL) applicators

{END - FRONT PANEL}

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BACK PANEL

DOG SQUEEZE ON FIPRONIL+CYPHENOTHRIN

[[Full or Partial Brand Name] contains Fipronil and Cyphenothrin to effectively kill fleas [(starts killing in as little as 1 hour)], ticks [(starts killing in as little as 1 hour)] [(including those that may transmit Lyme disease)], and kills [mosquitoes] [and] chewing lice. [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 up to 30 days on dogs.]

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS AND PUPPIES OVER 12 WEEKS OF AGE.



[[Full or Partial Brand Name] for dogs provides [four] [three] way protection that kills fleas, ticks, [mosquitoes] and chewing lice. Controls mites that may cause sarcoptic mange. Kills deer ticks that may transmit Lyme disease. Kills brown dog ticks, American dog ticks, and lone star ticks.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Causes moderate eye irritation. Do not get in eyes or on clothing. Harmful if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS. For external use only. Do not use on puppies under 12 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. [Some dogs may experience temporary startle effects when any product is applied.] Dogs 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. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, pregnant, nursing, debilitated or aged dogs. Call 1-800-781-4738 for 24-hour assistance.

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 further 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"> • Call a poison control center or 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.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-781-4738.

NOTE TO PHYSICIAN OR VETERINARIAN

Treat patient symptomatically

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BACK PANEL

**DOG SQUEEZE ON
FIPRONIL+CYPHENOTHRI**

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 [AND ENCLOSED DIRECTIONS] BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

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. Use entire contents off tube [vial] on each dog. [Do not split tubes 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. 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. Certain medications can interact with pesticides. 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. Separate the treated dog from all other dogs and cats for 24 hours after product has been applied. Cats and dogs that actively groom or engage in close physical contact with treated dog 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 dog and continue to monitor your dog for the next 24 hours. If symptoms persist call 1-800-781-4738 to talk to a veterinarian. Cats exhibiting these same symptoms from ingestion should be taken to the veterinarian immediately. If your dog is exhibiting signs of and/or are being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

Sensitivities may occur after using ANY pesticide product on dogs. Dogs may experience some temporary irritation at the site of product application. 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 by calling 1-800-781-4738.

{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: 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. Do not apply more often than once every [30 days] [month].

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



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BACK PANEL

**DOG SQUEEZE ON
FIPRONIL+CYPHENOTHRIN**

For Dogs Weighing up to 22 lbs. [including small dogs and puppies, 12 weeks or older]:

{For cartons containing 0.67 mL (0.023 fl oz) applicator tubes}

Apply one tube (.67 mL)(0.023 fl oz) [as a spot [on] [to] the dog's back between the shoulder blades][from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing [Between] 23[-] [to] 44 lbs.

{For cartons containing 1.34 mL (0.045 fl oz) applicator tube}

[Apply one tube (1.34 mL)(0.045 fl oz)] [as a spot [on] [to] the dog's back between the shoulder blades.] [from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing [Between] 45[-] [to] 88 lbs.

{For cartons containing 2.68 mL (0.091 fl oz) applicator tube}

Apply one tube (2.68 mL)(0.091 fl oz) [as a spot [on] [to] the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing [Between] 89[-] [to] 132 lbs.

{For cartons containing 4.02 mL (0.136 fl oz) applicator tube}

Apply one tube (4.02 mL)(0.136 fl oz) [as a spot [on] [to] the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

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 (starts killing in as little as 1 hour) for up to three months. Apply monthly if your dog 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 the first 7 days after application, then within 48 hours for up to 28 days.] [**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].

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.

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BACK PANEL

**DOG SQUEEZE ON
FIPRONIL+CYPHENOTHHRIN**

[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] [Patent(s) Pending]

Distributed by:
Sergeant's Pet Care Products, Inc.
P.O. Box 540399
Omaha, NE 68154-0399

[BAR CODE AREA]
EPA Reg. No. 2517-140
EPA Est. No. XXXXX-XX-XXX

{END - BACK / SIDE PANEL}

OPTIONAL OUTER PACKAGING

**DOG SQUEEZE ON
FIPRONIL+CYPHENOTHHRIN**

[How to Apply - 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.]

[Application Instructions] [Directions for Use]

How to open

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

1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube firmly to apply all of the solution [on] [to] the dog's skin [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.]

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OPTIONAL OUTER PACKAGING

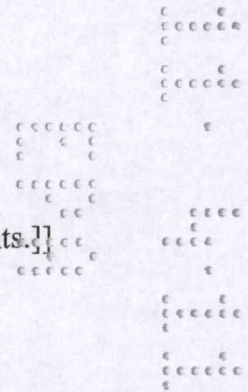
DOG SQUEEZE ON FIPRONIL+CYPHENOTHRIN

[Optional drawings that 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]

[1][2][3][4][5][6][12][24][Month [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] [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)]

[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.]

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OPTIONAL OUTER PACKAGING

DOG SQUEEZE ON FIPRONIL+CYPHENOTHRIN

[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



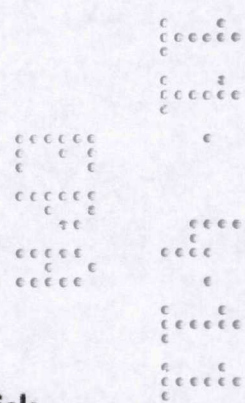
chewing lice



mosquitoes



mosquitoes



{END - OPTIONAL INSERT OR PACKAGE COPY}

TUBE/VIAL LABEL

DOG SQUEEZE ON FIPRONIL+ CYPHENOTHRIN

Front Label

Back Label

<p>{Brand Name}[cat graphic with line through] For dogs [up to X lbs][X-Y lbs] Fipronil 9.8% w/w, Cyphenothrin 5.2% w/w 0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or) 0.136 fl oz {label code}</p>	<p>KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open EPA REG. No. 2517-140 {label code}</p>
--	--