

2517-143

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. 2517-142
- Sergeant's Fipronil + Cyphenothrin + Nylar Squeeze-On for Dogs
EPA Reg. No. 2517-143

Applications dated September 26, 2011

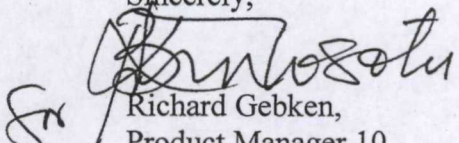
Dear Mr. Messina:

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,

A handwritten signature in black ink, appearing to read "Richard Gebken". To the left of the signature is a small, stylized handwritten mark that looks like "R".

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

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Sergeant's® Master Label

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Information in [] is optional.

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FRONT PANEL

DOG SQUEEZE ON

FIPRONIL+CYPHENOTHRIN+NYLAR

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

Sergeant's Fipronil + Cyphenothrin + Nylar Squeeze-On for Dogs

[ABNs]

[(Sergeant's®) (Sentry®) FRONTIER GOLD (Spot On) for dogs]
[(Sergeant's®) (Sentry®) Ectoadvance™ (Spot On) for dogs]

ACCEPTED

FEB 21 2012

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

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

EPA Reg. No. 2517-143

[Mosquitoes]

[•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]
[•A once monthly application is recommended for chewing lice.]
[•Rapid elimination of chewing lice infestations]

[Fleas]

[•Research demonstrates that [full or partial brand name] kills adult fleas (starts killing in as little as 1 hour), flea eggs, and flea larvae and prevents pupae development for up to [63 days] [9 weeks].]
[•[full or partial brand name] prevents development of all flea stages for up to [63 days][9 weeks].]
[•Kills flea eggs, [larvae] [and] [prevents pupae development] for up to [63 days][9 weeks]]
[•With Pyriproxyfen Insect Growth Regulator which Breaks the Flea Life Cycle]
[•With Pyriproxyfen to Break Flea Life Cycle]
[•With Insect Growth Regulator to Break Flea Life Cycle]
[•Dual Action [!]:Fipronil with Pyriproxyfen IGR Effectively Breaks the Flea Life Cycle]
[•Triple Action [!]: Effectively Breaks the Flea Life Cycle[!]]
[•Kills Fleas (starts killing in as little as 1 hour) up to [4 weeks!]] [2 months]]
[•Kills Flea Eggs & Flea Larvae [for more than 2 months]]
[•Prevents Flea Eggs From Developing Into Biting Adults]
[•Prevents development of all stages of the flea life cycle]

[Multiple Infestations]

[•Flea & Tick Control for Dogs & Puppies 12 weeks old and older]
[•Kills fleas (starts killing in as little as 1 hour), flea eggs, ticks (starts in as little as 1

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- hour), chewing lice & [mosquitoes]]
- [•Kills Fleas, Ticks and [mosquitoes]]
- [•Kills fleas (starts killing in as little as 1 hour), ticks (starts killing in as little as 1 hour), [mosquitoes], chewing lice, flea eggs, and larvae and prevents pupae development]
- [•Monthly flea, tick, mosquito, chewing lice, and flea egg protection]
- [•Monthly flea, tick, mosquito, and chewing lice protection]
- [•Kills fleas (starts killing in as little as 1 hour), ticks (starts killing in as little as 1 hour), [mosquitoes], flea eggs, and chewing lice]
- [• [Seven] [7] [Six][6][Five][5] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs,[&][and] flea larvae [&] [and] prevent the development of flea pupae]
- [• [Six] [6] [Five][5][Four][4]Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, [&][and] flea eggs [&] [and] flea larvae]
- [• [4 Week] [Flea and Tick & Treatment]]
- [• [Four (4) Week] [Flea, Tick, Mosquito and Chewing Lice Control]]
- [•When used monthly [full or partial brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations.]
- [• 4 week Flea and Tick Treatment!]
- [•Once A Month Flea and Tick Treatment]
- [• 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!]
- [• Kills Fleas (starts killing in as little as 1 hour), Ticks (starts killing in as little as 1 hour), Flea Eggs & Flea Larvae for up to [63 days] [9 weeks]]
- [•Prevents and controls reinfestations of listed pests for up to [1 month][4 weeks]]

[Ticks]

- [•Kills Ticks (starts killing in as little as 1 hour)]
- [•Kills Ticks including those that may transmit Lyme disease]
- [•Kills Ticks (starts killing in as little as 1 hour) for up to 4 weeks!]
- [•Kills [all stages of] Deer Ticks (vector of Lyme disease) for up to [4 weeks][1 month][30 days][per application]]
- [•[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 *Rhipicephalus sanguineus* for up to 4 weeks]
- [•Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to 4 weeks!]

[All Others]

- [•For Dogs and Puppies 12 weeks of age or older]
- [•For Dogs [4- 22 lbs], [23-44 lbs], [45-88 lbs], [89-132 lbs]
- [•Fast Acting]
- [•Waterproof]
- [•Long Lasting]
- [•If dog is at high risk for flea reinfestation a once month application may be needed]
- [•Apply Monthly]
- [•Controls mites that may cause sarcoptic mange]
- [One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][12 Applications][24Applications] and/or [1 Month]

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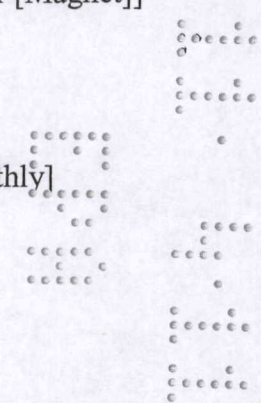
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Supply][2 Month Supply][3 Month Supply][4 Month Supply][5 Month Supply][6 Month
Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12
Week Supply][16 Week Supply][20 Week Supply][24 Week Supply][48 Week
Supply][52 Week Supply][104 Week Supply]

- [•Best if used year round!]
- [•(ICON Showing 4 Week Protection)]
- [•4 Week Dose!]
- [•1 Month Dose!]
- [•Easy to Use Application]
- [•Specially Formulated for Dogs and Puppies Over 12 Weeks]
- [•[Free] Calendar Stickers Inside!]
- [•Patented Technology]
- [•Apply once every [4 weeks]!]
- [•[Free with purchase] [Free inside] Monthly Application Reminder [Magnet]]
- [•Effective after bathing and exposure to water and sunlight]
- [•Fiponil (9.8%) + cyphenothrin (5.2%) + [pyrproxifen] (2.0%)]
- [•US and Foreign patents pending]
- [•Lift [here] for more information]
- [•For year round protection, apply (full or partial brand name) monthly]
- [Full or Partial Brand Name] is a trademark of [Company Name]



[[1][2][3][4][5][6][12][24] Applications]
 [For use ONLY on dogs] [&][and][puppies]
 [4[-][to] 22 lbs]
 [23[-][to]44 lbs]
 [45[-][to]88 lbs]
 [89[-][to]132 lbs]
 [over 12 weeks of age]

[For Dogs & Puppies (12 weeks or older and) 4 [-][to] 22 lbs.]
 [For Dogs 23[-][to]44 lbs.]
 [For Dogs 45[-][to]88 lbs.]
 [For Dogs 89[-][to]132 lbs.]

ACTIVE INGREDIENTS:

Fipronil.....	9.8%
Cyphenothin.....	5.2%
Pyriproxifen	2.0%
OTHER INGREDIENTS[*]:	83.0%
TOTAL	100.0%

[*diethylene glycol monoethyl ether, vitamin E nicotinate]

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

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KEEP OUT OF REACH OF CHILDREN WARNING

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

NET CONTENTS:

Contains

[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 ⋮

BACK PANEL

DOG SQUEEZE ON

FIPRONIL+CYPHENOTHIN+NYLAR

[BACK/SIDE CARTON LABEL - MASTER LABEL]

[full or partial brand name] contains Fipronil, Cyphenothin and the insect growth regulator (IGR) Pyriproxyfen to effectively kill Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], and kills flea eggs, flea larvae, [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 [1 month] [[4] [four] weeks] on dogs.

READ ENTIRE LABEL BEFORE EACH USE.

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. 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 treatment. 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.

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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">• Immediately call a poison control center or doctor.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Have person sip a glass of water if able to do so.• 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

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. 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. Do not use on puppies under 12 weeks of age. Use entire contents of tube [vial] on each dog. [Do not split one tube between dogs.] 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. **Best if used year round.** 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 treatment 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.

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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 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: 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][30 days].

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



BACK PANEL

DOG SQUEEZE ON FIPRONIL+CYPHENOTHRIN+NYLAR

For Dogs Weighing 4 [-][to] 22 lbs. [including small dogs and puppies, 12 weeks or older]
{For cartons containing .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 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 to kill mosquitoes] [infestations]. [full or partial brand name] kills fleas (starts killing in as little as 1 hour) for up to two months. If your pet is at high risk for flea reinfestation [, or in a

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highly infested environment], apply monthly. 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 treatment, 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 [4 weeks][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.]

[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. 2517-143
EPA Est. No. XXXXX-XX-XXX

[BAR CODE AREA]

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[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.]

[{Outer Packaging}]

[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.

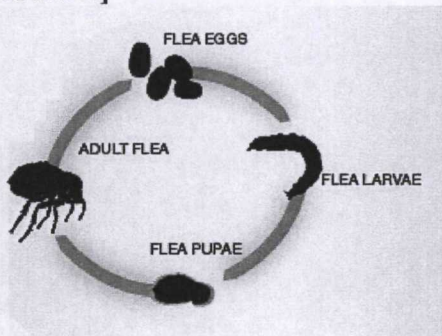
How to apply:

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

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



[Flea life cycle diagram] [Flea Life Cycle][Sample coloring and layout may be different on final label]



[Look at the Label (Look at the Label icon) 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 [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)]

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[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)]


[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.]


 Adult Flea


 Adult Flea

 flea eggs


 flea eggs

 flea larvae


 flea larvae


 flea pupae

 flea pupae

 ticks


 ticks

 Brown Dog Tick


 Brown Dog Tick


 Deer Tick


 Deer Tick


 American Dog Tick


 American Dog Tick


 chewing lice

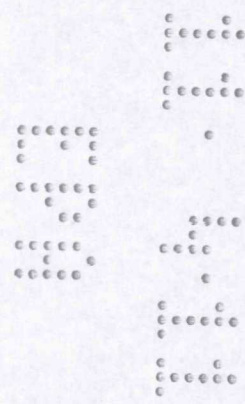
 chewing lice

 Lone Star Tick

 Lone Star Tick

 mosquitoes

 mosquitoes




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

{END}

TUBE / VIAL LABEL

Front Label

Back Label

<p>{Brand Name} </p> <p>Fipronil 9.8% w/w, Cyphenothrin 5.2% w/w, Pyriproxyfen 2.0% 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 WARNING: Read directions and precautions before using. Use scissors to open. EPA REG. No. 2517-143 {label code}</p>
--	--