

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

JUL 2 1 2014

#### VIA EMAIL

James Messina Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138

Subject: Submission of Label Amendment to Add Additional Marketing Claims and Update CSF

Product Name: Cyphenothrin Squeeze-On for Dogs (20%)

EPA Reg. Number: 2517-131 Submission date: January 28, 2014

Decision Number: 487325

Dear Mr. Messina:

The label amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is <u>acceptable</u>.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Products released for shipment after 18 months from the date on this notice or the next printing of the master label whichever occurs first, must bear the new revised label. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA. Amended labeling will supersede all previously accepted labels. Your release for shipment of this product constitutes acceptance of these conditions. As required by 40 CFR 156.10(a)(6), you must submit one copy of the final printed label before the product is released for shipment. If you have any questions please contact Carlyn Petrella by phone at (703) 347-0439 or via email at "petrella.carlyn@epa.gov".

Sincerely,

Richard Gebken

Product Manager 10

Insecticide Branch

Office of Pesticide Programs

Richard J. Ceelle

Date: July 21, 2014

21 Apr 2014

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### FRONT PANEL

Page 1 of 8 DOG SOUEEZE ON

Cyphenothrin

[Optional text appears in brackets - the final label may include some or all of the optional text on front, back or side label panels]

## Cyphenothrin Squeeze-On for Dogs (20%)

### [ABNs]

[Sergeant's Flea and Tick Squeeze-On for Dogs and Puppies Over 12 Weeks Old (20%)]

[Sergeant's Flea and Tick Squeeze-On for Dogs (20%)]

[Sergeant's Squeeze-On for Dogs and Puppies Over 12 Weeks Old (20%)]

[Sergeant's Squeeze-On for Dogs (20%)]

[Sergeant's AdvanSpot<sup>TM</sup> Flea and Tick Squeeze-On for Dogs and Puppies Over 12 Weeks Old

[Sergeant's AdvanSpot<sup>TM</sup> Flea and Tick Squeeze-On for Dogs (20%)]

[Sergeant's AdvanSpot<sup>TM</sup> Squeeze-On for Dogs and Puppies Over 12 Weeks Old (20%)]

[Sergeant's AdvanSpot<sup>TM</sup> Squeeze-On for Dogs (20%)]

[Sergeant's PetArmor® FastAct® for Dogs (20%)]

[Sergeant's PetArmor® FastAct® Squeeze-On for Dogs (20%)]

[Sergeant's VetSpot for Dogs (20%)]

[Sergeant's Silver® Flea and Tick Squeeze-On for Dogs and Puppies Over 12 Weeks Old

[Sergeant's Silver® Flea and Tick Squeeze-On for Dogs (20%)]

[Sergeant's Silver® Squeeze-On for Dogs and Puppies Over 12 Weeks Old (20%)]

[Sergeant's Silver® Squeeze-On for Dogs (20%)]

[Sentry Flea and Tick Squeeze-On for Dogs and Puppies Over 12 Weeks Old (20%)]

[Sentry Flea and Tick Squeeze-On for Dogs (20%)]

[Sentry Squeeze-On for Dogs and Puppies Over 12 Weeks Old (20%)]

[Sentry Squeeze-On for Dogs (20%)]

[Sentry PetArmor® FastAct® for Dogs (20%)]

[Sentry PetArmor® FastAct® Squeeze-On for Dogs (20%)]

[Sentry VetSpot for Dogs (20%)]

/ [VetSpot for Dogs (20%)]

· [PetArmor® FastAct® for Dogs (20%)]

[PetArmor® FastAct® Squeeze-On for Dogs (20%)]

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



[1.5 x 1.5 cm or as indicated above]

For use ONLY on dogs and puppies 9 - 20 lbs and 12 weeks of age or older {OR}

For use ONLY on dogs [21 - 39 lbs] [40 - 60 lbs] {OR}

Only for use on dogs and puppies over 12 weeks of age and 9 lbs to 20 lbs {OR}

Only for use on dogs [21 lbs to 39 lbs] [40 lbs to 60 lbs]

[[Three] [3] Way Protection [Kills fleas, ticks, and repels mosquitoes]]

[Three in one Protection! [Kills fleas, ticks, and repels mosquitoes]]

[Specially Formulated for Dogs and Puppies over 12 weeks old]

[Flea & Tick Control for Dogs & Puppies 12 weeks old and older]

[For Dogs & Puppies (Over 12 Weeks of Age) greater than 9 lbs]

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[For [Small] Dogs & Puppies (Over 12 Weeks of Age) 9 to 20 lbs]

[For [Medium] Dogs & Puppies (Over 12 Weeks of Age) 21 to 39 lbs]

[For [Large] Dogs & Puppies (Over 12 Weeks of Age) 40 to 60 lbs]

[For Dogs [more than 9 lbs] or [9 lbs to 20 lbs] or [21 lbs to 39 lbs] or [40 lbs to 60 lbs]]

[[12][15][18][21][24][32][52] Week Supply For Dogs]

[Monthly flea and tick control]

[Works for up to 4 Weeks!]

[Protects for up to 4 Weeks!]

[Apply every [4 weeks] [1 month][30 days]!]

[Up to 4 week Dose!]

[Up to 1 Month Dose!]

[Three Applications {for cartons with 3 applicators}] and/or [3 Month Supply] or [12 Week

[Four Applications {for cartons with 4 applicators}] and/or [4 Month Supply] or [16 Week

Supplyl

[Best if used year round!]

[Easy to Use Application]

[Patented Technology] [Patent pending technology]

[Dogs can be bathed 24 hours after squeeze-on is applied.]

[Ouick Drying] [formula]

[with Vitamin E]

[No oily residue]

[Fragrance Free]

[[Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]]

[Clean cut [open] [tube][vial][applicator][pipette]]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette][!]]

[Satisfaction Guaranteed]

[If you are not satisfied, we will make it right with a replacement or refund.]

## [Multiple infestations]

[Kills fleas and ticks and repels mosquitoes]

[Kills Fleas [in as little as 1 hour] [and] Ticks [in as little as 3 hours] [Repels Mosquitoes]

[Protects for up to 4 Weeks on fleas and ticks!]

[Protects for up to 4 Weeks on adult fleas and ticks!]

[Up to 4 Week Flea and Tick Treatment!]

[Up to 4 Week Flea and Tick Control]

[Up to 4 Week Flea and Tick Protection!]

[Up to [One] Month Flea and Tick Treatment]

[Kills Fleas and Ticks for up to 4weeks!]

[Kills Adult Fleas and Ticks for up to 4 weeks!]

[Starts killing fleas and ticks in [less than] [just] 5 minutes [after application]

[Starts killing fleas and ticks in [less than] [just] 15minutes [after application]

[Starts killing fleas and ticks in [less than][just] | hour [after application]

[Starts to kill fleas and ticks in [less than][just][1 hour]]

[Quickly kills fleas in [less than] [just] [1 hour] and ticks in [as little as][just] 3 hours]]

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### [Fleas]

[Starts killing fleas in [less than][just] 5 minutes [after application]

[Starts to kill fleas in [less than][just] 5 minutes [after application]]

[Starts killing fleas in [less than][just]15 minutes [after application]

[Starts to kill fleas in [less than][just] 15 minutes [after application]]

[Starts to kill fleas in less than 1 hour] [after application]]

[Stops][Prevents] fleas [from biting][before they bite][dogs][your dog]

[Prevents fleas from ingesting a blood meal]

[Stops fleas from biting which may cause anemia]

[Stops fleas from biting which may cause [flea allergy] dermatitis]

[[Stops][Prevents] flea allergy dermatitis [resulting from][caused by][flea bites][biting fleas]

[Kills fleas before they [can] bite]

[Quickly kills fleas in [less than] [just] [1 hour]]

[Kills fleas in as little as 1 hour!]

[Kills Fleas for up to 4 weeks!]

### [Ticks]

[Starts killing ticks in [less than][just] 5 minutes [after application]

[Starts to kill ticks in [less than][just] 5 minutes [after application]]

[Starts killing ticks in [less than][just] 15 minutes [after application]

[Starts to kill ticks in [less than][just]15 minutes [after application]]

[Starts killing ticks in less than 1 hour] [after application]

[Quickly kills ticks in [less than] [just] 3 hours]

[Kills ticks in 3 hours [after application][!]

[Kills and Detaches Ticks]

[Prevents ticks from attaching and feeding in as little as [3 hours] after application]

[[Kills ticks] in as little as 3 hours!]

[Kills Ticks for up to [4 weeks][1 month][30 days]][!]]

[Kills Ticks [including Deer Ticks] [including those that may transmit Lyme disease] for up to [4 weeks][1 month][30 days]]

[Kills Deer Ticks (vector of Lyme Disease) 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 Brown Dog Ticks [(Rhipicephalus sanguineus)] 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 for up to [30 days] [4 weeks] [1 month]!]

[Repels mosquitoes]

[Repels mosquitos within 24 hours]

[Repels mosquitos that may transmit heartworm]

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

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

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

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#### **ACTIVE INGREDIENTS:**

 Cyphenothrin [(CAS# 39515-40-7)].
 .20.00%

 OTHER INGREDIENTS[\*]:
 80.00%

 [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

NET CONTENTS: XXX fl oz (XXX mL) [X-Y fl oz [tubes][applicators][pipettes][vials]] [THREE][FOUR][SIX][TWELVE]

[0.05 fl oz (1.5 mL) [X-Y fl oz [tubes][applicators][pipettes][vials]]

[0.10 fl oz (3.0 mL) [X-Y fl oz [tubes][applicators][pipettes][vials]]

[0.15 fl oz (4.5 mL) [X-Y fl oz [tubes][applicators][pipettes][vials]]

**{END - FRONT PANEL}** 

BACK/SIDE PANEL

DOG SQUEEZE ON Cyphenothrin

[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> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>	
IF ON SKIN OR CLOTHING	<ul> <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 SWALLOWED	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to do so.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>	

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#### 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. Do not use on cats or animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 12 weeks of age or less than [9 lbs][21 lbs][40 lbs]. Use entire contents of [tube] [vial][applicator][pipette] 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.

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.

[1.5 x 1.5 cm or as indicated below]

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 veterinarian immediately.

{Outer Packaging}

### [[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea and tick protection where it needs to be.]

How to open: Remove product [tube][vial][applicator][pipette][s] from the package. [Separate one [tube][vial][applicator][pipette] from the others.] [Holding][Hold] the [tube][vial] [applicator][pipette] 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][applicator] [pipette] 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][vial][applicator][pipette] over dog and use open end to part dog's hair. Squeeze [tube][vial][applicator][pipette] 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.

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## Frequency of Application:

[When used monthly, [product name][this product] controls flea and tick infestations.] A once monthly application is recommended where mosquito control is needed.

# Only For Dogs Weighing Between 9 and 20 lbs Do not apply to dogs less than 9 lbs. {For cartons containing one 1.5 mL (0.05 fl oz) applicator tubes}

Apply one [tube][vial][applicator][pipette] (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] [as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.].

# Only For Dogs Weighing Between 21 and 39 lbs Do not apply to dogs less than 21 lbs. {For cartons containing two 1.5 mL (0.05 fl oz) applicator tubes}

[Apply two [tube][vial][applicator][pipette]s (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].

### OR

### {For cartons containing one 3.0 mL (0.10 fl oz) applicator tube}

[Apply one [tube][vial][applicator][pipette] (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] [as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.].

# Only For Dogs Weighing Between 40 and 60 lbs Do not apply to dogs less than 40 lbs. {For cartons containing three 1.5 mL (0.05 fl oz) applicator tubes}

[Apply two [tube][vial][applicator][pipette]s (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].

#### OR

### {For cartons containing one 4.5 mL (0.15 fl oz) applicator tube}

[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] [as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades.][This allows for a more direct application to the skin.].

#### STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Do not remove [tube] [vial] [applicator] [pipette] from the pack until ready to use. Store in a cool (below 25°C) dry place inaccessible to 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 or for disposal instructions. Never place unused product down any indoor or outdoor drain

[Brand name][This product] is an effective and easy to use product. [As with all flea and tick control products [Brand name][this product] 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.]

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Information in [ ] is optional.

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#### **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 outside of box]
[Made in USA] [Manufactured in USA]

[Made in the USA For:] or [Manufactured by:] [Distributed by:] Sergeant's Pet Care Products, Inc. Omaha, NE 68138-3710

EPA Reg. No. 2517-131 EPA Est. No. XXXXX-XX-XX [lot, date & label code] [UPC CODE]

{END - BACK / SIDE PANEL}

# OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGING DOG SQUEEZE ON CYPHENOTHRIN

(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 for 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][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>][Ninth][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.]

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Information in [ ] is optional.

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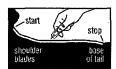
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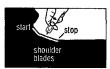
[Optional graphics below may or may not appear anywhere on finished label]

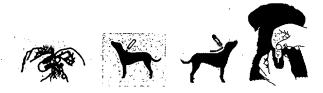
<b>F</b>	Adult Flea	
*	Ticks	
*	Brown Dog Tick	
*	Deer Tick	<b>(4)</b>
*	American Dog Tick	<b>®</b>
1	Mosquitoes	













{END - BACK / SIDE PANEL}

#### TUBE AVIATE LABOR

## DOG SQUEEZE ON CYPHENOTHRIN

**Front Label** 

Back Label



{Brand Name}

For Dogs [x-y lbs] ≥12 wks

Cyphenothrin 20.0%

0.05 fl oz (or) 0.10 fl oz (or) 0.15 fl oz {label code}

KEEP OUT OF REACH OF CHILDREN
CAUTION: Read directions and precautions
before using. Use scissors to open.
EPA REG. No. 2517-131 {label
code}