

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 14, 2015

Mr. Kelly R. Hoskins Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138-3710

Subject: Label Amendment – Addition of sublabel for veterinarian use and other minor changes Product Name: SERGEANT'S FIPRONIL + ETOFENPROX SQUEEZE-ON FOR DOGS EPA Registration Number: 2517-153 Application Date: 01/06/2015 Decision Number: 499064

Dear Mr. Hoskins:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Elizabeth Fertich at 703-347-8560 or via email at fertich.elizabeth@epa.gov.

Sincerely,

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Jennifer Saunders, PhD, Product Manager 4 Invertebrate and Vertebrate Branch 1 (IVB1) Registration Division (7505P) Office of Pesticide Programs

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Information in [] is optional.

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL+ETOFENPROX

[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.] {Information is instructional}

Sergeant's Fipronil + Etofenprox Squeeze-On for Dogs

{Market Label-the word Dog will be at least 40-75% in height of the largest letter in the primary brand name.} {Market Label-a large clear picture of a dog in the respective weight range will be on the front panel of the label}

{1.5cm x1.5cm or as indicated below}

[Apply to puppies over 13 weeks old] [Apply to puppies 13 weeks or older]



For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] {OR} For use ONLY on dogs [[&][and] puppies 4[-] [to] 22 lbs and over 13 weeks of age {OR} ONLY For Dogs [23[-][to] 44 lbs] [45[-][to] 88 lbs] [89[-] [to] 132 lbs] {OR} ONLY For Dogs & Puppies 13 weeks or older [&][and] 4[-][to] 22 lbs {Market Label-one of the statements above will be placed prominently on the front panel}

{box only designates Vet Only language}

{**SUBLABEL:** FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION}

FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels. Not for residential use. Do not repackage.

[Ideal for shelter use when under direct supervision of veterinarian]
[Professional Roll Pack]
[Convenient roll pack for in clinic use]
[Convenient roll pack for animal facility use]
[For use only by licensed veterinarians]

[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice] [Rapid elimination of chewing lice infestation]

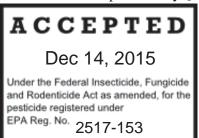
[Fleas]

[Kills adult Fleas [for up to three months]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills Adult Fleas, which may be a source of [flea allergy dermatitis] [and] [, flea bite anemia]] [Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If dog is a high risk for flea reinfestation a once month application may be needed]



Sergeant's Master Label4DEC15 2 YR EXTVersion 15.1aEPA No. 2517-153Information in [] is optional.Page 2 of 10EPA SAL 4/15/2014

[Ticks]

[Kills ticks including those that may transmit Lyme disease] [Kills Ticks for Up to [4 weeks] [1 month] [30 days]!] [Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]] [Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]] [Kills [brown dog ticks], [American dog ticks,] [and] [lone star ticks][,][and deer 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]!] [Multiple Infestations] [Kills chewing lice [and aids in control of mites that may cause sarcoptic mange]] [Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 13 weeks old and older] [Kills fleas, ticks, chewing lice [&] [and] [mosquitoes]] [Kills Fleas, Ticks [&] [and] [Mosquitoes]] [Kills fleas, ticks, [mosquitoes] [and] [chewing lice]] [Monthly flea, tick, [mosquito], and chewing lice [application] [treatment] [[Four] [4] [Three] [3] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] and chewing lice] [[4 Week] [1 month] [30 day] [Flea and Tick [Application] [Treatment]] [[Four (4) Week] [1 month] [30 day] [Flea Tick, and Chewing Lice Control] [[Four (4) Week] [1 month] [Flea, Tick, [Mosquitoes] and Chewing Lice Control] [Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!] [Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice] [Application] [Treatment]] [Use [**Brand Name**][this product] monthly to control ticks and chewing lice] [Monthly flea, tick, [mosquito], and chewing lice protection.] [Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!] [Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!] [All Others]

[For Dogs and puppies 13 weeks of age or older] [Can be used on puppies 13 weeks of age and older] [Specially Formulated for Dogs and Puppies 13 weeks of age or older] [Only For Small Dogs 4 to 22 lbs.] [Only For Medium Dogs 23-44 lbs.] [Only For Large Dogs 45-88 lbs.] [Only For Extra Large Dogs 89-132 lbs.] [Fast Acting] [Long Lasting] [Convenient spot treatment] [Easy to Use [Application]] [Best if used year round!] [For year-round protection, apply [**Brand Name**][this product] monthly] [(ICON Showing 4 Week Protection)] [Apply monthly] [Prevents infestation of fleas, ticks, and chewing lice for [1 month][4 weeks]] [Apply once every [4 weeks] [month] [30 days]!] [4 Week Dose!] [1 Month Dose!] [30 Day Dose!] [One Application][Two Applications][Three Applications][Four Applications][Five

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ACTIVE INGREDIENTS:

Fipronil	
Etofenprox	
OTHER INGREDIENTS:	<u>75.20%</u>
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

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

Net Contents: X fl oz [Y – X fl oz [tube][vial][applicator][pipette][s]] [1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

OR {box only designates Vet Only language}

Net Contents: X fl oz X count [Y – X fl oz [tube][vial][applicator][pipette][s]] [Thirty-five] 35[Fifty][50][Seventy-five][75][One hundred][100] [One hundred sixty 160]

[0.023 fl oz (0.67 mL) [tube][vial][applicator][pipette][s]] [0.045 fl oz (1.34 mL) [tube][vial][applicator][pipette][s]] [0.091 fl oz (2.68 mL) [tube][vial][applicator][pipette][s]] [0.136 fl oz (4.02 mL) [tube][vial][applicator][pipette][s]]

{END - FRONT PANEL}

BACK / SIDE PANEL

DOG SQUEEZE ON FIPRONIL+ETOFENPROX

[[**Brand Name**] [This product]contains fipronil to effectively kill fleas and ticks [(including those that may transmit Lyme disease).] [The active ingredient in [**Brand Name**][this product] features 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 13 WEEKS OF AGE.

[[**Brand Name**][This product] for dogs provides [[four] [three] way] protection that kills fleas, ticks, [mosquitoes] and chewing lice. Aids in control of mites that may cause sarcoptic mange. Kills deer ticks that transmit Lyme disease. Kills brown dog ticks, American dog ticks, and lone star ticks. Prevents flea reinfestation for [[4][four] weeks] [[1] [one]month] [30 days].]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. 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.

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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.

OR {box only designates Vet Only language}

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 a dog with more than one pesticide product at a time. Over dosing a dog can result in serious illness and even death. Use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction. If the dog is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

FIRST AID			
If On Skin	Take off contaminated clothing.		
Or Clothing	• Rinse skin immediately with plenty of water for 15-20 minutes.		
	• Call a poison control center or doctor for treatment advice.		
If Swallowed	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.		
If In Eyes	• 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.		
	HOT LINE NUMBER		
Have the produc	t 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 p	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, rabbits and animals other than dogs. Do not allow [your] dog to ingest this product. Do not use on puppies under 13 weeks of age or less than [4][23][45][89] lbs. Use entire contents of [tube] [vial] [applicator] [pipette] on each dog. [Do not split one [tube] [vial] [applicator] [pipette] between dogs.] Do not use multiple [tube] [vial] [applicator] [pipette]s on one dog. Weigh [your] dog to be

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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 1-800-781-4783. 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. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

{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][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. Do not apply more often than once every [4 weeks][30 days][month].

Only For Dogs Weighing 4[-][to] 22 lbs. Do not apply to dogs weighing less than 4 lbs. [including small dogs and puppies, 13 weeks or older]:

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

Apply one [tube][vial][applicator][pipette] (0.67 mL)(0.023 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades] [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 23 [-] [to] 44 lbs. Do not apply to dogs weighing less than 23 lbs. {For cartons containing 1.34 mL (0.045 fl oz) applicator tube}

Apply one [tube][vial][applicator][pipette] (1.34 mL)(0.045 fl. oz.) [directly to skin] [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades] [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 45 [-] [to] 88 lbs. Do not apply to dogs weighing less than 45 lbs. {For cartons containing 2.68 mL (0.091 fl oz) applicator tube}

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

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between the shoulder blades] [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 89[-] [to] 132 lbs Do not apply to dogs weighing less than 89 lbs. Do not use two tubes on dogs greater than 132 lbs{For cartons containing 4.02 mL (0.136 fl oz) applicator tube}

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

FREQUENCY OF APPLICATION

Use [**Brand Name**] [this product] monthly for complete control of flea, tick [and] chewing lice [and mosquito] infestations. [Studies show that] [**Brand Name**][this product] kills adult fleas 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. [**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.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: 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 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.]

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

[Distributed by:][Manufactured by:] Sergeant's Pet Care Products, Inc. Omaha, NE 68138-3710 [Coupon(s) inside or on outside of box] [Made in USA]

[BAR CODE AREA][Lot code] EPA Reg. No. 2517-153 EPA Est. No. [2517-NE-001] [2517-NE-002] [XXX-XX-XXX]

{END - BACK / SIDE PANEL}

OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE	DOG SQUEEZE ON
	FIPRONIL+ETOFENPROX
[How to Apply - May contain graphics illustrating product use, e.g., e.g.,	dog with a drop falling
onto its neck from a vial on front, side, or back carton label and/or a	pplicator labeling.]

[[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.]

[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][vial][applicator][pipette] over dog and use open end to part dog's hair.
- 2. Squeeze [tube][vial][applicator][pipette] 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.]

[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] to avoid chance of ingestion
- [6] Do NOT split [tube][vial][applicator][pipette]s between pets[and use the ENTIRE [tube] [vial] [applicator] [pipette] contents]

[Brand Name]

[1][2][3][4][5][6][12][24] [Month [Treatment] [Application] Tracker] [Carecard]
[For year-round protection, apply [**Brand Name**][this product] monthly.]
[[Pet's][Dog's] Name (Empty blank for owner to fill in name)]

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[Dog's Weight (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] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)]

[Application date][Date of Application]

[calendar stickers with [Brand Name].

[Place stickers on your calendar as a reminder to reapply [**Brand Name**] in 30 days.]

[Place sticker on your calendar or [refrigerator] to remind yourself to apply [Brand name][this product] to your dog]

[Monthly Application Reminder Magnet (image of reminder magnet)]

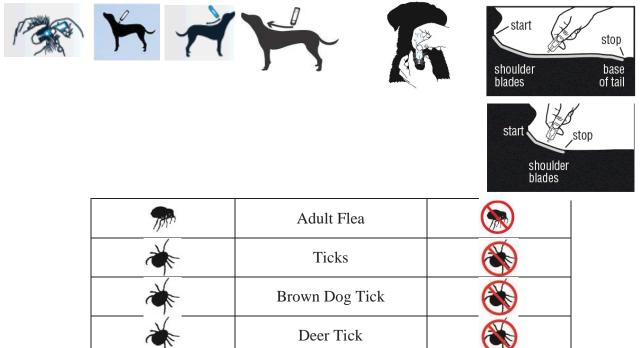
[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [**Brand Name**][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

{END - OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE}

OUTER PACKAGING OR INSERT COPY

DOG SQUEEZE ON FIPRONIL+ETOFENPROX

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



American Dog Tick

Chewing Lice

Sergeant's Master Label					
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Information	Information in [] is optional. Page 10 of 10		EPA SAL 4/15/201	4	
	*	Lone Star Tick			
	- The	Mosquitoes			
	×.	Mite			



{END - OPTIONAL INSERT OR PACKAGE COPY}

TUBE/VIAL LABEL

DOG SQUEEZE ON FIPRONIL+ETOFENPROX

Front Label	Back Label	
{Brand Name} For dogs [X-Y lbs] ≥13 wks	KEEP OUT OF REACH OF CHILDREN	
Fipronil 9.8%, Etofenprox 15.0%	CAUTION: Read directions and precautions before	
0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz	using. Use scissors to open.	
(or) 0.136 fl oz {label code}	EPA REG. No. 2517-153 {label code}	
{EPA REG No may be on either the front or back label}		

er the front or

{END – TUBE/VIAL COPY}