

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 5, 2021

Prince M. Bamaze Regulatory Affairs Sergeant's Pet Care Products, LLC 10077 South 134<sup>th</sup> Street Omaha, NE 68138-3710

Subject: Label Amendment – Registration review mitigation language, addition of sublabel

and optional marketing statements.

Product Name: Sergeant's Bifenthrin + Nylar Shampoo for Dogs

EPA Registration Number: 2517-138 Application Date: 05/22/2018, 01/12/2021

Decision Number: 541475, 569592

#### Dear Prince Bamaze:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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.

The Agency, in accordance with FIFRA, as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product in connection with the Bifenthrin Final and/or Interim Decision, and has concluded that your submission is acceptable.

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 12 months from the date of this letter. After 12 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

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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 with FIFRA section 6. If you have any questions, please contact Stephanie Suarez by phone at 703-347-8221, or via email at <a href="mailto:Suarez.Stephanie@epa.gov">Suarez.Stephanie@epa.gov</a>.

Sincerely,

Kable Bo Davis Senior Regulatory Specialist Registration Division (7505P) Office of Pesticide Programs

Enclosure

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FRONT PANEL DOG SHAMPOO
Bifenthrin + Nylar Shampoo

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

#### Sergeant's® Bifenthrin + Nylar Shampoo for Dogs

#### {ABNs}

[SENTRY®PRO XFT Flea and Tick Shampoo for Dogs]

[SENTRY®PRO Flea and Tick Shampoo for Dogs]

[SENTRY®PRO Flea and Tick Shampoo for Dogs & Puppies]

[SENTRY® Fiproguard® MAX Flea and Tick Shampoo for Dogs]

[SENTRY® Fiproguard® MAX Flea and Tick Shampoo for Dogs<sub>II</sub>]

[SENTRY® Fiproguard® MAX<sub>II</sub> Flea and Tick Shampoo for Dogs]

[SENTRY® Fiproguard® Plus Flea and Tick Shampoo for Dogs]

[SENTRY® Fiproguard® Plus Flea and Tick Shampoo for Dogs<sub>II</sub>]

ISENTRY® Fiproguard® Plus<sub>II</sub> Flea and Tick Shampoo for Dogs1

SENTRY® Fiproguard® Plus<sub>II</sub> Flea and Tick Snampoo for Dogs]

[SENTRY® Fiproguard® Plus IGR Flea and Tick Shampoo for Dogs]

[SENTRY®Vet Plus Flea and Tick Shampoo for Dogs]

[PetArmor® Plus For Dogs FastAct Flea and Tick Shampoo]

[PetArmor® Plus For Dogs Flea and Tick Shampoo]

[PetArmor® Plus For Dogs Shampoo]

[PetArmor® Plus FastAct Flea and Tick Shampoo For Dogs]

[PetArmor® Plus Flea and Tick Shampoo For Dogs]

[PetArmor® Plus Shampoo For Dogs]

[PetArmor® FastAct Treatment]

[PetArmor® FastAct Flea & Tick Treatment

[PetArmor® FastAct Shampoo Treatment]

[PetArmor® FastAct Shampoo]

[PetArmor® FastAct Flea & Tick Shampoo

[PetArmor® FastAct Shampoo for Dogs]

[PetArmor® FastAct Treatment for Dogs]

[PetArmor® FastAct Shampoo Treatment for Dogs]

[Apply to puppies over 12 weeks old]

[Apply to puppies 12 weeks or older]

#### [Optional Marketing Claims]

[Kills [adult] fleas for [15 days][2 weeks]][1 week][7 days]

[Active against fleas]

[Active against ticks]

[Controls fleas]

[Controls ticks]

[Kills [black-legged (or) deer] ticks, lone star ticks, and brown dog ticks.]

[Kills brown dog ticks [Rhipicephalus sanguineus] for up to [15 days][2 weeks] [which may carry

Rocky Mountain spotted fever]

[Kills Fleas [&] Ticks] [and continues to kill] for [7 days] [1 week]]

[Kills [flea eggs] [and] [flea larvae] for 30 days]

[Kills for 30 days [flea eggs][and][flea larvae]

[Kills Fleas [for [15 days] [2 weeks]], Ticks [for [7 days] [1 week]], [flea eggs [for 30 days]] [and]

[flea larvae [for 30 days]]

[Kills fleas and ticks for [7 days][1 week][and] flea eggs [and larvae] for 30 days]



#### ACCEPTED

08/05/2021

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

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[Repels and prevents blood feeding by mosquitoes for up to 2 weeks]

[Repels mosquitoes [for [up to] [2 weeks] [15 days]] [1 week] [7 days]

[Prevents blood feeding by mosquitoes for [up to] [15 days][2 weeks]]

[Kills Ticks for [7 days] [1 week]]

[Kills fleas, ticks, flea eggs and (flea) larvae]

[Kills flea eggs and (flea) larvae for (30 days) (1 month)]

[Kills adult Fleas [for [up to] [15 days] [2 weeks]]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills fleas, source of flea allergy dermatitis] [, flea bite anemia] [and tapeworm infestations]]

[Kills Fleas Up to [[15 days] [2 weeks]!]

[7-day protection] [1 week protection]

[15-day flea protection]

[Sterilizes (All New) Fleas and Kills Their Eggs For 30 Days]

[Breaks The Flea Life Cycle!]

[Kills Ticks That May Carry Lyme disease]

[pH Balanced For Dog's Coat]

[Fast Acting]

[Cleans][Deodorizes][Conditions]

[Contains [Pyriproxyfen][Nylar®] Insect Growth Regulator (IGR)]

[Kills Flea Eggs [and] [Flea Larvae] for 30 Days]

[Kills Fleas [&] [and] Ticks]

[For Dogs]

[Cleans, Deodorizes and Conditions]

[One Step Hassle Free Protection!]

[Protection Against All Stages of the Flea Life Cycle]

[Prevents Reinfestation for up to 30 Days]

[Controls Reinfestation for up to 30 Days]

[Kills Fleas, Ticks & Flea Eggs While Grooming Your Dog]

[Formulated for Dogs and Puppies (over 12 weeks old)]

[[Sergeant's]Caring For Your Pets since 1868]

[The Only Flea and Tick Protection You Need For Your Dog!]

[[Specific Fragrance noted here] Scent]

[Quick relief from [fleas] [ticks] [and] [mosquitoes]]

[Quick relief plus [7-day] [1 week] protection]

[[Plus] 7-day protection] [[Plus] kills for 7 days]

[[Plus] prevents reoccurrence for [7 days] [1 week]]

[Starts working quickly]

[[Kills and] washes away fleas & ticks [through contact]

[Kills through contact]

[Continues to kill new fleas and ticks for [1 week][7 days][after application]]

[shampoo][treatment][for dogs]

[Effectively cleanses dog of fleas and ticks]

[Proven effective on fleas and ticks for [7 days][1 week]

[Proven effective through testing]

[Visible proof it's working]

[Repels mosquitoes that may transmit heartworm disease]

[Repels mosquitoes so they can't bite]

[Convenient] [One-handed][No drip] [squeeze bottle] [Pours only when squeezed.]

[Easy] [With flip open cap.]

[Peel here]

[Life can be overwhelming but your dog's flea and tick [protection] [treatment] shouldn't be.]

[Enjoy your next adventure with peace of mind.]

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**ACTIVE INGREDIENTS:** 

Bifenthrin	0.050%
Pyriproxyfen	0.015%
OTHER INGREDIENTS:	<u>99.935%</u>
[TOTAL	100.000%]

# 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)

{END - FRONT PANEL}

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#### **BACK PANEL**

DOG SHAMPOO Bifenthrin + Nylar Shampoo

## READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS.

[Kills fleas for [up to] [15 days] [2 weeks] [and] ticks for [up to] [7 days][1 week]]

[Kills the ticks that may carry Lyme Disease]

[pH balanced for [pet's][dog's] coat]

[Cleans [and][deodorizes][and][conditions]]

[Repels mosquitoes and prevents blood feeding for [up to] [15 days[2 weeks]]

#### [IMPORTANT CONSUMER INFORMATION]

[**Product Name**] [This product] kills fleas [for [15 days][2 weeks]] [, ticks for [7 days][1 week] [, and repels mosquitoes and prevents blood feeding [for [up to] [15 days] [2 weeks]] while it cleans and deodorizes in one easy and convenient step.] [This rich, conditioning, non-staining formula contains a highly effective flea and tick killing ingredient combined with an insect growth regulator (IGR) that sterilizes new fleas and kills their eggs for 30 days.]

[[Bathing a dog can be tricky. That's why we've designed an easy, one-handed squeeze bottle with a flip open cap.] [Spend less time wrestling with your dog and more time providing the comfort and protection that he needs from pesky [fleas] [ticks][and][mosquitoes].] [[It's simple. They're family. And family is everything.] [[brand name] makes it simple to care for your furry family from home.] [[This product][Brand name] Provide[s] the comfort and protection your dog needs from pesky [fleas][ticks][and][mosquitoes].]

[[This product][Brand name] kills fleas and ticks quickly and continues to kill them for up to [7 days] [1 week].] [It also kills flea eggs and larvae for 30 days which prevents new adult fleas from developing.] [See the fleas and ticks leave your pet and get washed down the drain.] [A clean dog with a healthy coat is a welcome member of the family.] [You'll love this [fragrance] scented shampoo.]

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION:** Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 12 weeks of age. Do not treat your dog with more than one pesticide product at a time. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing dogs. Sensitivities may occur after using ANY pesticide product for dogs. If signs of sensitivity occur bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately by calling {xxx-xxx-xxxx}. DO NOT USE ON CATS.

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FIRST AID		
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 treatment advice.	
IF ON SKIN	Take off contaminated clothing.	
OR	Rinse skin immediately with plenty of water for 15-20 minutes.	
CLOTHING:	Call a poison control center or doctor for treatment advice.	
HOT LINE NUMBER		
Have the prod	uct container or label with you when calling a poison control center or doctor or going for	

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact {xxx-xxx-xxxx} for emergency medical treatment information.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### {Option #1}

Wet dog's coat thoroughly with water. Use 1 tbsp of shampoo for every 7 lbs of the dog's body weight. Rub shampoo into coat and down to the skin starting at the head and working back. [Keep out of dog's eyes.] Work up a lather and add more water if necessary to increase lathering. Allow lather to stand 10 minutes, then rinse completely and towel dry. Do not reapply more often than once a week.

Application of product on pets must only be done indoors.

#### {Option #2}

Weigh and determine your dog's body weight in pounds. Do not use on puppies under 12 weeks of age. Wet dog's coat thoroughly. [Use the reference table below as a guide to determine the amount of **[PRODUCT NAME]** [This product] [shampoo] to use on your dog.] [Use ½ oz of **[PRODUCT NAME]** [This product] [shampoo] for every 7 pounds of dog body weight.] A volume of ½ fl oz is equivalent to 1 Tablespoon (tbsp.) of shampoo. For a typical 10 lb. dog, apply 1.0 fl oz or 2 Tablespoons (tbsp.) of shampoo to the dog. Starting at the head and working back, work up a lather with this quick lathering formula, being sure that the lather is worked thoroughly into dog's coat down to the skin. Allow lather to stand [ten] [10] minutes, then rinse completely and towel dry. Kills fleas and ticks quickly and continues to kill adult fleas for [up to] [15 days] [2 weeks] and ticks for [up to][7 days] [1 week], [while the IGR][and] continues to break the flea life cycle for [30 days][1 month] [to prevent the reinfestation process]. To maintain maximum effectiveness against both fleas and ticks, repeat (or reapply) every 30 days.

Application of product on pets must only be done indoors.

#### [Optional table]

[Optional table]		
Use [½ fl oz][1 tbsp] of [PRODUCT NAME][This product][shampoo] for every 7 pounds of		
dog body weight (lbs).		
Amount	of shampoo	Dog's body weight in pounds (lb)
fluid ounces	(tablespoons)	
½ fl oz	(1 tbsp)	Up to 7 lb
1 fl oz	(2 tbsp)	Over 7 lbs to 14 lbs
2 fl oz	(4 tbsp)	Over 14 lbs to 28 lbs
3 fl oz	(6 tbsp)	Over 28 lbs to 42 lbs
4 fl oz	(8 tbsp)	Over 42 lbs to 56 lbs
5 fl oz	(10 tbsp)	Over 56 lbs to 70 lbs
6 fl oz	(12 tbsp)	Over 70 lbs to 84 lbs
7 fl oz	(14 tbsp)	Over 84 lbs to 98 lbs
8 fl oz	(16 tbsp)	Over 98 lbs to 112 lbs

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Over 126 lbs to 140 lbs

#### STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Store only in original container in a cool, dry area inaccessible to children and pets and away from heat and sunlight.

(20 tbsp)

**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:** Do not pour or dispose down-the-drain or sewer. Call your local solid waste agency for local disposal options.

#### **[WARRANTY]**

10 fl oz

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.]

[Our company heritage dates back over 150 years. Polk Miller, a pharmacist and pet lover, started by formulating pet health products for his own dogs in 1868. We continue that tradition today by providing products and services that help take the guesswork out of pet parenting.]

[Packaged with care by pet lovers [in Omaha, Neb.]] [{brand name} protection guarantee icon] [Protection Guarantee] [If you're not satisfied with {brand name}, let's talk!] [We'll gladly provide you with a refund.]

[{brand name} Cares [about your experience!] [We care about your experience, please contact us with any questions.]

[Need Help?] [We are your [application and treatment] [flea & tick] experts!] [website] [facebook icon] [twitter icon] [youtube icon] [instagram] [QR code]

[[Text [xxxxx] to [xxxxx]] [or] [visit] [website address] [to sign up for] [for access to] [tips][how to apply videos] [application reminders][reminders][coupons] [and more]].

[Questions or medical emergency: 1-800-XXX-XXXX]

[For an] Emergency [?] [call] [1-] 800-781-4738 [Coupon(s) inside or on outside]

[Non-Emergency] [?] [call] [1-] 800-224-7387

[If you have questions or comments about this product, please write: [Sergeant's][SENTRY] Consumer Response, Omaha, NE 68138.]

[Distributed by:] [Manufactured by:] Sergeant's Pet Care Products, LLC P.O. Box 540399, Omaha, NE 68154-0399 [Made in USA]
EPA Reg. No. 2517-138
EPA Est. No. XXXXX-XX-XX
[lot, date & label code] [UPC CODE]

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[Each optional graphic below may or may not appear anywhere on the label]



Adult Flea



ticks



flea eggs



flea eggs



flea larvae



fleas



ticks



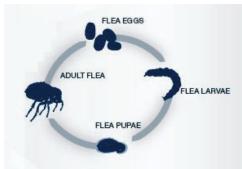
flea larvae



mosquitoes



mosquitoes







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# **(OPTIONAL COMBO KIT MARKETING STATEMENTS AND GRAPHICS – MAY OR MAY NOT APPEAR ANYWHERE ON THE BUNDLE PACKAGE LABELING)**

#### **{FRONT PANEL}**

{ABNs}

PetArmor 3-step Treatment Kit
PetArmor Complete Treatment Kit
PetArmor Flea & Tick Treatment Kit
PetArmor Total Treatment Kit
PetArmor Treatment Kit

[Shampoo & Home Spray] [Flea & Tick Shampoo & Home Spray]

Step 1: Treat dog with {Brand Name Shampoo}

Step 2: Control indoor environment with {Brand Name Home Spray}

**Step 3:** Prevent [reoccurrence] [future outbreaks], [[\$x] [BONUS!] Coupon inside for {Brand Name Topical or Collar}]

[Contains: 1 {Brand Name Shampoo}, XX fl oz (XXX mL), EPA Reg. No. xxx-xxx &1 {Brand Name Home Spray}, XX fl oz (XXX mL), EPA Reg. No. yyy-yyyy [BONUS! Coupon inside]] {OR}

[{Brand Name} is a promotional combination of the following registered products: {Product A, EPA Reg. No. xxxx-xxx; Product B, EPA Reg. No. yyy-yyyy]

#### {BACK OR SIDE PANELS}

[Fleas & Ticks can happen to even the most prepared pet parents.] [Tackle [tough] flea & tick outbreaks [with the {Kit Brand Name}.]] [Follow these 3 [easy] steps]]

#### [[Step 1:

<u>[Treat</u> your dog with {Brand Name Shampoo} to provide quick comfort & relief from fleas & ticks.] [Kill fleas & ticks for up to 7 days & prevent reinfestation by killing flea eggs & larvae for 30 days.]

#### Step 2:

[Control your environment with {Brand Name Home Spray}.] [If fleas & ticks are on your dog it's likely they are also in the home.] [Use [{Brand Name Home Spray}] [This product]] on indoor areas your dog frequents to kill fleas & ticks, & prevent eggs from developing.]

#### Step 3:

<u>Prevent</u> the reoccurrence of fleas & ticks on your dog by maintaining a regular regimen of protection. [Apply a long-lasting topical solution or collar.] [[\$x] [BONUS!] coupon [for {Brand Name Topical or Collar}] inside this kit.]]

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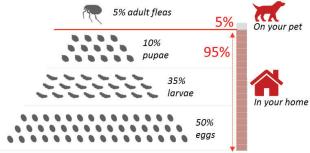
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#### [Did you know?]

[Adult fleas represent only 5% of the flea population. What you don't see are the other life stages (eggs, larvae, pupae) that could be lurking on your dog or in your home. Break the cycle with products that also kill eggs.] [Remember, treating your home is an essential step for complete flea & tick protection.] [It's important to protect your dog and your home.] [95% of fleas live in pre-adult stages in the pet's environment]

<example of optional infographic>





#### [What To Look For]

[Fleas: Flea dirt (small dark flakes), excessive itching or scratching, redness and inflammation, hot spots and pale gums. Adult fleas on your dog's coat and skin.] [Ticks: Ticks like dark places on your dog. Check inside the ears, under the tail, collar, arms and leg folds. Use a flea comb for a thorough inspection.]



[Both fleas and ticks are small but dangerous. A serious infestation can cause your dog to become anemic.]

[Some dogs may have sensitivity to flea saliva and can have allergic reactions, leading to painful and intense itching. Fleas can also transmit a variety of diseases such as tapeworms.] [Tick bites may also trigger allergic reactions, but even more dangerous are the diseases they can transmit like Lyme disease.]

[Coupon(s) inside or on outside of bundle package]

[Our company heritage dates back over 150 years. Polk Miller, a pharmacist and pet lover, started by formulating pet health products for his own dogs in 1868. We continue that tradition today by providing products and services that help take the guesswork out of pet parenting.]

[Packaged with care by pet lovers [in Omaha, Neb.]] [{brand name} protection guarantee icon] [Protection Guarantee] [If you're not satisfied with {brand name}, let's talk!] [We'll gladly provide you with a refund.]

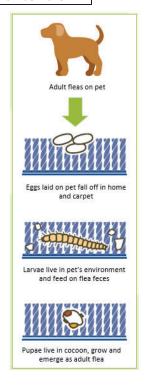
[{brand name} Cares [about your experience!] [We care about your experience, please contact us with any questions.]

[Need Help?] [We are your [application and treatment] [flea & tick] experts!]

[website] [facebook icon] [twitter icon] [youtube icon] [instagram] [QR code]

[[Text [xxxxx] to [xxxxx]] [or] [visit] [website address] [to sign up for] [for access to] [tips] [how to apply videos] [application reminders] [reminders] [coupons] [and more]].

[Questions or medical emergency: 1-800-XXX-XXXX]



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[For an] Emergency [?] [call] [1-] 800-781-4738 [Non-Emergency] [?] [call] [1-] 800-224-7387

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

[Made in USA]

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

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

{END - Bundle Pack Label}