UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 18, 2017

Aaron Johnson, DVM, MS Senior Research Scientist Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140

Subject: Label Amendment – Revisions to organization and mitigation Product Name: Parastar For Dogs EPA Registration Number: 70585-12 Application Date: 1-Sep-16 Decision Number: 521112

Dear Dr. Johnson:

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 Julie Breeden-Alemi, DVM at 703-347-0511 or via email at <u>Breeden-Alemi.Julie@epa.gov</u>.

Sincerely,

Elizabet Fatul

Elizabeth Fertich Acting Product Manager 03 Invertebrate & Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

Enclosure

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

## **CARTON FRONT PANEL**

Parastar<sup>TM</sup> For Dogs

For Dogs [(fipronil)]



{Note to Reviewer: The word "Dogs" will be included in the product name and will be at least 75% the height of the largest letter in the product name.}

A large, clear picture of a dog in the weight range for the product as packaged will be on the front panel.

{Note to Reviewer: Only one of the two sentences shown below will appear in a box on the carton front panel.}

Apply only to dogs and puppies more than 8 weeks old and [weighing] [4-22 lbs] [23-44 lbs] [45-88 lbs] [89-132 lbs] Apply only to dogs and puppies 8 weeks or older and [weighing] [4-22 lbs] [23-44 lbs] [45-88 lbs] [89-132 lbs]

{Note to Reviewer: See Optional Marketing Claims list at the end of the label.}

<b>ACTIVE INGREDIENTS:</b>	
Fipronil	9.7 %
INERT INGREDIENTS:	90.3%
TOTAL:	100.0%

### KEEP OUT OF REACH OF CHILDREN CAUTION

See Back [Panel] [Label Panel] for full Directions for Use, First Aid and Precautionary Statements

### **NET CONTENTS:**

[Contains] [1] [One] [2] [Two] [Three] [3] [4] [Four] [5] [Five] [6] [Six] [12] [Twelve] [24] [Twenty-Four] [-] 0.023 fl oz (0.67 ml) tube[s] [Contains] [1] [One] [2] [Two] [Three] [3] [4] [Four] [5] [Five] [6] [Six] [12] [Twelve] [24] [Twenty-Four] [-] 0.045 fl oz (1.34 ml) tube[s] [Contains] [1] [One] [2] [Two] [Three] [3] [4] [Four] [5] [Five] [6] [Six] [12] [Twelve] [24]

[Twenty-Four] [-] 0.091 fl oz (2.68 ml) tube[s]

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



OR



{Note to reviewer – Cat icons indicated above appear at lower right hand corner of carton front panel. Size of Cat icons are  $1.5 \times 1.5$  cm or greater in size. Either a YELLOW box or a RED box is used, whichever provides better contrast with the other carton colors.}

# CARTON BACK PANEL

Parastar<sup>TM</sup> [For Dogs] contains fipronil to effectively kill fleas and ticks [[(]including those that may transmit Lyme Disease[)]]. [This product features a sustained-release formula for fast-acting [and long-lasting] control of [fleas], [ticks], [mosquitoes] and [chewing lice] [for up to [1 month] [4 weeks] on dogs].

### READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE AND [WEIGHING] [ 4 [to] [-] 22 lbs] [23 [-] [to] 44 lbs] [45[-] [to] 88 lbs] [89 [-] [to] 132 lbs].

[Parastar<sup>TM</sup> For Dogs provides [four-] [three-] way protection that kills [fleas], [ticks], [mosquitoes] and [chewing lice]. Controls mites that may cause sarcoptic mange. Kills deer ticks [that transmit Lyme disease]. Kills brown dog ticks, American dog ticks, and lone star ticks. Prevents flea reinfestation.]

### Side Effects

Monitor your dog after application. [Some dogs may experience temporary startle effects when 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 a sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these or other side effects occur, consult your veterinarian or call Elanco US Inc. at 1-888-545-5973. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment.

{Note to Reviewer: A box labeled "Side Effects" will be placed immediately above the cat warning box on the back panel}



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

{Note to reviewer – Cat warning text box with cat prohibition icons indicated above appear at lower right hand corner of carton front panel. Size of Cat icons are 1.5 x 1.5 cm or greater in size. Either a YELLOW box or a RED box is used, whichever provides better contrast with the other carton colors.}

OR

For Technical Information call: 1-888-545-5973 [hours of service] [Manufactured in the USA] [Formulated in the USA]

[Distributed by] [Manufactured for][Available exclusively from]: Elanco US, Inc. 2500 Innovation Way Greenfield, IN 46140

EPA Reg. No. 70585-12 EPA Est. NO. XXXXX-XX-XXX [BAR CODE AREA]

## **INSIDE FLAP OF CARTON BACK PANEL**

FIRST AID	
If swallowed	Call a poison control center or a 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 to 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	Wash with plenty of soap and water. Get medical attention if irritation
	persists.
	HOTLINE NUMBER
Have the produc	ct container or label with you when calling a poison control center or doctor, or

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 1-888-545-5973.

### **PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS. CAUTION.** Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. 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 only. Individual sensitivities, while rare, may occur after using any pesticide product. Certain medications can interact with pesticides. Do not treat your dog with more than one topically applied pesticide product at a time. Consult a veterinarian before using on medicated, debilitated or aged dogs. Can be used on breeding, pregnant, or lactating dogs. Consult a veterinarian before using on dogs with known organ dysfunction.

### **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 CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. Do not allow your dog to ingest this product. Do not bath dogs until 24 hours after treatment

Do not apply to puppies less than 8 weeks of age. Do not apply to dogs or puppies weighing less than [4][23][45][89] lbs. For use only on dogs [[&] [and] puppies] [weighing 4 [-] [to] 22 lbs]

[weighing 23 [-] [to] 44 lbs.] [45 [-] [to] 88 lbs.] [weighing 89 [-] [to] 132 lbs.] Do not split one [tube][vial] between dogs. [Do not use multiple [tubes][vials] on one dog.] Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Do not double dose or apply more than one tube per treatment for one dog regardless of the dog's weight

**How to open:** Remove product [tube[s]] [vial[s]] 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:** While holding the dog with one hand, use the other hand to apply the solution. Invert the [tube] [vial] and use the open end to part the dog's hair. Apply contents of one [tube] [vial] of Parastar<sup>TM</sup> [For Dogs] [as a spot to the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail]. Hold the dog for a few seconds to give the solution time to be absorbed into the dog's coat. When finished, wrap the [tube] [vial] in paper and put into the trash. Apply only one tube per dog per treatment. Repeat application may be made if necessary, but do not apply more often than once every 30 days.

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

### **FREQUENCY OF APPLICATION**

Use Parastar<sup>TM</sup> [For Dogs] monthly for control of [flea], [tick] [and] [chewing lice] [and mosquito] infestations. [Studies show that] Parastar<sup>TM</sup> [For Dogs] kills fleas for up to three months. If your dog is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly. Apply monthly to control [ticks], [mosquitoes] and [chewing lice]. [ Parastar<sup>TM</sup> [For Dogs] Kills mosquitoes [within 48 hours for up to 1 month]] Parastar<sup>TM</sup> [For Dogs] remains effective, after water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

{For Cartons containing .67 ml (0.023 fl oz) tubes}

**For use only on Dogs and Puppies 8 weeks old or older Weighing 4 [to] [-] 22 lbs.** Apply one tube [0.023 fl. oz. [(0.67 mL)]] [(0.67 mL) (0.023 fl. oz.)] [0.67 mL [(0.023 fl. oz.)]] [from the back of the neck to a point midway between the neck and tail.] [as a spot on the dog's back between the shoulder blades.]

{For Cartons containing 1.34 ml (0.045 fl oz) tubes}

**For use only on Dogs and Puppies 8 weeks old or older Weighing 23** [-] [to] 44 **lbs.** Apply one tube [0.045 fl. oz. [(1.34 mL)]] [(1.34 mL) (0.045 fl. oz.)] [1.34 ml [(0.045 fl. oz.)]] [from the back of the neck to a point midway between the neck and tail.] [ as a spot on the dog's back between the shoulder blades.]

{For Cartons containing 2.68 ml (0.091 fl oz) tubes} For use only on Dogs and Puppies 8 weeks old or older Weighing 45[-] [to] 88 lbs. Apply one tube [0.091 fl. oz. [(2.68 mL)]] [(2.68 mL) (0.091 fl. oz.)] [2.68 mL [(0.091 fl. oz.)]] [from the back of the neck to a point midway between the neck and tail.] [ as a spot on the dog's back between the shoulder blades.]

{For Cartons containing 4.02 ml (0.136 fl oz) tubes}

**For use only on Dogs and Puppies 8 weeks old or older Weighing 89**[-] [to] **132 lbs** Apply one tube [0.136 fl. oz. [(4.02 mL)]] [(4.02 mL) (0.136 fl. oz.)] [4.02 mL [(0.136 fl. oz.)]] [from the back of the neck to a point midway between the neck and tail.] [as a spot on the dog's back between the shoulder blades.]

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or 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:** Non-refillable container. Do not reuse or refill this container. If empty: Place in the trash or 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

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of ELANCO US, INC. (EUS) or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold EUS and Seller harmless for any claims relating to such factors.

EUS warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or EUS, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, EUS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with State law, in no event shall EUS or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE

LIABILITY OF EUS AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF EUS OR SELLER, THE REPLACEMENT OF THE PRODUCT.

[If you have questions or comments about this product, please write to: Elanco US, Inc., (address).]

# OPTIONAL TEXT FOR CARTON BACK PANEL OR INSIDE FLAP OF CARTON BACK PANEL

{Note to Reviewer: text in the following section may be used in addition to, not as a replacement for, the required text shown in carton back panel and inside flap of carton back panel sections above.}

# 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.

### How to Open:

**1.** Remove product [tube[s]] [vial[s]] from the package.

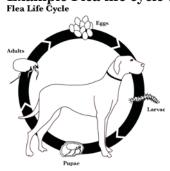
**2.** [Separate one [tube] [vial] from the others.] Hold the [tube] [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

### How to Apply:

1. Invert [tube] [vial] over dog and use open end to part dog's hair.

**2.** Squeeze [tube] [vial] firmly to apply all of the solution to the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

## Example Flea life cycle diagram – actual may differ slightly



Look at the Label (Look at the Label icon)

[Easy] [6] [Six-] [Step] [Parastar<sup>TM</sup> [For Dogs]] [Spot-on] [Squeeze-On] 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. To avoid chance of ingestion, separate treated dogs from each other and other pets until product is dry.
- 6. Do NOT split tubes between dogs.

Parastar<sup>TM</sup> [For Dogs]

Monthly reminder card [Fill out this reminder card with your dog's name and the date each treatment should be given to your dog as a reminder to reapply [Parastar<sup>TM</sup> [For Dogs]] every 30 days.] [optional graphics that may or may not appear on label] Apply [Parastar<sup>TM</sup> [For Dogs]] monthly. Dog's Name (Empty blank for owner to fill in name) First [dose] [Treatment] (Empty blank for owner to fill in date) Second [dose] [Treatment] (Empty blank for owner to fill in date) Third [dose] [Treatment] (Empty blank for owner to fill in date) Fourth [dose] [Treatment] (Empty blank for owner to fill in date) Fifth [dose] [Treatment] (Empty blank for owner to fill in date) Sixth [dose] [Treatment] (Empty blank for owner to fill in date) Seventh [dose] [Treatment] (Empty blank for owner to fill in date) Eighth [dose] [Treatment] (Empty blank for owner to fill in date) Ninth [dose] [Treatment] (Empty blank for owner to fill in date) Tenth [dose] [Treatment] (Empty blank for owner to fill in date) Eleventh [dose] [Treatment] (Empty blank for owner to fill in date) Twelfth [dose] [Treatment] (Empty blank for owner to fill in date)

calendar stickers with Parastar<sup>TM</sup> [For Dogs]

[1] [2] [3] [4] [5] [6] [12] [24] -month] [application tracker]

Apply Parastar<sup>TM</sup> [For Dogs] monthly. Place stickers on your calendar as a reminder to reapply Parastar<sup>TM</sup> [For Dogs]] in 30 days.

It's time for Parastar<sup>TM</sup> [For Dogs]] [!]

Enclosed for your convenience [is] [are] [1] [2] [3] [4] [5] [6] [12] [24] [one] [two] [three] [four] [five] [six] [twelve] [twenty-four] sticker[s].] [Place stickers on your calendar every 30 day from initial treatment as a reminder to reapply Parastar<sup>TM</sup> [For Dogs] every 30 days.

Optional Example graphics for calendar stickers, reminder cards, and/or magnets.



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 Parastar<sup>TM</sup> [For Dogs]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.

## TUBE LABEL

### FRONT OF TUBE:



OR: Dog [[.045][.091] [.136] fl. oz.][[.67][1.34][2.68][4.02] mL]

OR: weighing [23-44] [45-88][89-132] lbs.

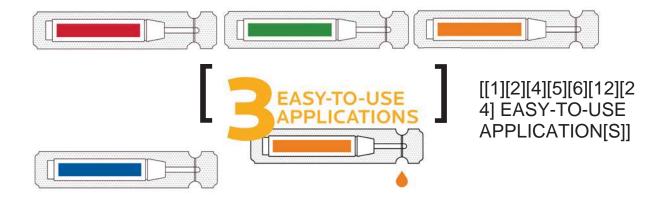
BACK OF TUBE:

KEEP OUT OF REACH OF CHILDREN CAUTION: Read accompanying directions and precautions before using. Use scissors to open. EPA REG. No. 70585-12 EPA EST. NO. XXXXX-XXX {label code}

# OPTIONAL LABEL GRAPHICS

[Example pictograms that may or may not be found on the printed label]







## OPTIONAL MARKETING CLAIMS

### Mosquitoes

1. Kills mosquitoes [within 48 hours for up to 1 month]

## Adult Fleas

- 1. Kills [adult] fleas [for up to [three] [3] months] [!]
- 2. Kills newly emerged adult fleas before they lay eggs
- 3. Kills fleas [, a source of flea allergy dermatitis] [, flea bite anemia]
- 4. Kills fleas [for] up to [4 weeks] [1 month] [30 days] [!]
- 5. If dog is a high risk for flea reinfestation apply once-a-month application

### Ticks

- 1. Kills ticks, including those that may transmit Lyme disease
- 2. Kills ticks for up to [[4] [four] weeks] [1 month] [30 days]!
- 3. Kills deer ticks [that may transmit Lyme disease,] for up to [[4] [four] weeks] [l month] [30 days]
- 4. Kills ticks (including deer ticks) for up to [[4] [four] weeks] [1 month] [30 days]
- 5. Kills [brown dog ticks], [American dog ticks,] [[and] lone star ticks]
- 6. Kills ticks
- 7. Kills [brown], [American dog,] [and] [lone star,] ticks [(*Rhipicephalus sanguineus*)] for up to [[4] [four] weeks] [1 month] [30 days]
- 8. Kills American dog ticks [(*Dermacentor variabilis*)] for up to [[4] [four] weeks] [1 month] [30 days]!

## Multiple Infestations

- 1. Kills [chewing lice] [and] [[C][c]ontrols mites that may cause sarcoptic mange]
- 2. [Flea] [&] [and] [tick] control only for dogs [&] [and] [puppies 8 weeks old and older and [ 4 [to] [-] 22 lbs] [23 [-] [to] 44 lbs] [45[-] [to] 88 lbs] [89 [-] [to] 132 lbs]]
- 3. [Flea] [&] [and] [tick] control only for dogs [&] [and] [puppies more than 8 weeks old and [ 4 [to] [-] 22 lbs] [23 [-] [to] 44 lbs] [45[-] [to] 88 lbs] [89 [-] [to] 132 lbs]]
- 4. Kills [fleas], [ticks] [&] [and] [chewing lice] [&] [and] mosquitoes
- 5. Kills [fleas] [,] [&] [and] [ticks] [and mosquitoes]
- 6. Kills [fleas], [ticks] [,] [&] [and] [chewing lice] [and] [mosquitoes]
- 7. Kills [fleas], [ticks], [mosquitoes] and [chewing lice]
- 8. Monthly [flea], [tick], [mosquito], and [chewing lice] [treatment]
- 9. [Four] [4] way control kills fleas, ticks, mosquitoes and chewing lice
- 10. [Three] [3]way control kills fleas, ticks, and chewing lice
- 11. [4-Week] [l-month] [30-day] [flea] [and] [&] [tick] treatment
- 12. [Four [4] [-] Week] [l-month] [flea], [tick], [mosquito], [and] [&] [chewing lice] control
- 13. Kills [fleas] and [ticks] for up to [[4] [four] weeks] [1 month] [30 days]!
- 14. Once-a-month [flea] and [tick] treatment
- 15. Use [Parastar<sup>TM</sup> [For Dogs]] monthly to control [ticks] and [chewing lice]
- 16. Use [Parastar<sup>TM</sup> [For Dogs]] monthly to control [fleas], [ticks] and [chewing lice]

- 17. Monthly [flea], [tick], [mosquito], [and] [&] [chewing] [lice].
- Parastar<sup>TM</sup> [For Dogs]] provides convenient and effective [flea], [tick] [,] [&] [and] [chewing lice] [and mosquito] control only for dogs and puppies 8 weeks and older and [weighing] [4 [to] [-] 22 lbs] [23 [-] [to] 44 lbs] [45[-] [to] 88 lbs] [89 [-] [to] 132 lbs].

All Others

- 1. For use only on dogs and puppies [more than 8 weeks old and [weighing] [4 [to] [-] 22 lbs] [23 [-] [to] 44 lbs] [45[-] [to] 88 lbs] [89 [-] [to] 132 lbs]]
- 2. For use only on dogs and puppies [8 weeks old and older and [weighing] [4 [to] [-] 22 lbs] [23 [-] [to] 44 lbs] [45[-] [to] 88 lbs] [89 [-] [to] 132 lbs]
- 3. Fast[-]Acting
- 4. Long[-]Lasting
- 5. Prevents [flea] reinfestation of listed pests for [1 month] [4 weeks]
- 6. [Controls] [Treats] and prevents infestation of listed pests for [4 weeks][1 month]
- 7. [Controls] [Treats] existing infestation and prevents establishment of additional infestation of listed pests
- 8. Convenient spot treatment
- 9. Once-a-month treatment
- 10. A once monthly application for chewing lice.
- 11. Fast action against chewing lice infestations
- 12. Controls mites that may cause sarcoptic mange
- [One Application] [Two Applications] [Three Applications] [Four Applications] [Five Applications] [Six Applications] [Twelve Applications] [Twenty-Four Applications] and/or [1-month supply] [2-month supply] [3-month supply] [4-month supply] [5-month supply] [6month 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] or [[1] [2] [3] [4] [5] [6] [12] [24] applications]
- 14. Best if used year round!
- 15. 4[-]week dose[!] [in Child Resistant Packaging]
- 16. 1[-]month dose[!] [in Child Resistant Packaging]
- 17. 30[-]day dose[!] [in Child Resistant Packaging]
- 18. A fipronil product
- 19. fipronil (9.7%)
- 20. Contains fipronil[,] [-] the active ingredient in Fipaira for Dogs\*
- 21. \*Parastar<sup>TM</sup> [For Dogs]] is not manufactured by or distributed by Merial. Fipaira for Dogs is a registered trademark of Merial
  {Note to Reviewer: When the two statements above (with \*) are used, both statements will

{Note to Reviewer: When the two statements above (with \*) are used, both statement be used and they will appear on the same panel}

- 22. Formulated for dogs and puppies older than 8 weeks and [4 [to] [-] 22 lbs] [23 [-] [to] 44 lbs] [45[-] [to] 88 lbs] [89 [-] [to] 132 lbs]
- 23. Fast-acting, long-lasting that's also waterproof.
- 24. [1] [2] [3] [4] [5] [6] [12] [24] Easy-to-Use Applications [!] [in Child Resistant Packaging]
- 25. Easy-to-use [application]
- 26. [Free] calendar stickers inside!
- 27. [Free] calendar stickers inside

- 28. Apply once every [4 weeks] [month] [30 days]!
- 29. Waterproof
- 30. Can be used on breeding, pregnant and lactating [dogs] [bitches] [female dogs]
- 31. [Free] Monthly application reminder magnet inside
- 32. Can be used only on puppies more than 8 weeks of age and [ 4 [to] [-] 22 lbs] [23 [-] [to] 44 lbs] [45[-] [to] 88 lbs] [89 [-] [to] 132 lbs]
- 33. Can be used only on puppies 8 weeks of age and older and [ 4 [to] [-] 22 lbs], [23 [-] [to] 44 lbs], [45[-] [to] 88 lbs], [89 [-] [to] 132 lbs]
- 34. Monthly application reminder card inside
- 35. Optional graphics: Images of the different kinds of bugs killed with a line drawn through
- 36. Dogs [N][n]eed [A][a]dventure[!]
- 37. Adventure [P][p]ack
- 38. Tick and Flea [P][p]rotection for [A[[a]dventurous [D][d]ogs
- 39. Protection [P][p]ack
- 40. Protection from [H][h]ead to [T][t]oe
- 41. This [adventure][protection] pack contains [1] [2] [3] [4] [5] [6] [12] [24] [a single] dose[s] of Parastar<sup>TM</sup> for Dogs along with other valuable offers [to help ensure that your dog is always [ready for adventure][covered].

For use only on Dogs & Puppies 8 weeks or older and weighing [4 [to] [-] 22 lbs] [23 [-] [to] 44 lbs] [45[-] [to] 88 lbs] [89 [-] [to] 132 lbs]

EPA[approval date]