

70585-12

03-31-2011

1/12



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAR 31 2011

Novartis Animal Health
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

SUBJECT: Label Notification – Addition of a Graphic per PR Notice 98-10
NAH2/Parastar, EPA Reg. No. 70585-12
Decision: D446411

Dear Mr. Ross Gilbert:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated February 23, 2011, for the product Parastar. The Registration Division has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6701 or Rosanna Louie-Juzwiak of my staff at 703-308-0037.

Sincerely,

for A handwritten signature in cursive script, appearing to read "Richard Gebken".

Richard Gebken
Product Manager 10, Insecticide Branch
Registration Division (7504P)
Office of Pesticide Programs



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70585-12	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Novartis Animal Health US, Inc. / Parastar™	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Novartis Animal Health US, Inc. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application.

Notification - Explain below. Other - Explain below.

NOTIFICATION

MAR 3 1 2011

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of an addition of a graphic per PR Notice 98-10. This notification is consistent with the provisions of PR 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Should you have any questions, please contact me at (e-mail) Ross@PyxisRC.com or (phone) 253-853-7369.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container 0.67, 1.34, 2.68, 4.02 ml. 3	If "Yes" Package wgt. No. per container

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container
2.01, 4.02, 8.04, 12.06 ml.

5. Location of Label Directions
 On Label
 On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph Paper glued Stenciled Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Ross Gilbert	Title Agent	Telephone No. (Include Area Code) 253-853-7369
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Certification
 I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

3. Title
Agent

4. Typed Name
Ross Gilbert

5. Date
2/23/11

6. Date Application Received (Stamped)

[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]

Parastar™

NOTIFICATION

[Apply to puppies more than 8 weeks old]

MAR 3 1 2011

[Apply to puppies 8 weeks or older]

[Mosquitoes]

- [[Kills mosquitoes] [within 24 hours] [within 24 hours for up to the first 7 days after treatment, and within 48 hours for up to 28 days]]

[Adult Fleas]

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

[Ticks]

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

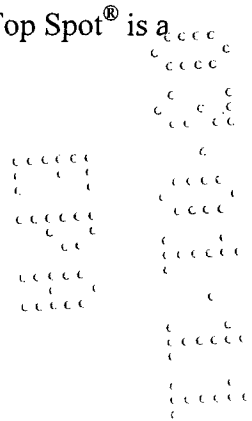
[Multiple Infestations]

- [Kills [chewing lice] and [controls mites that may cause sarcoptic mange]]
- [[Flea] [&] [and] [tick] control for dogs [&] [and] [puppies 8 weeks old and older] [more than 8 weeks old]]
- [Kills [fleas], [ticks] [&] [and] [chewing lice] [&] [and] mosquitoes]
- [Kills [fleas] [,] [&] [and] [ticks] [and] mosquitoes]
- [Kills [fleas], [ticks] [,] [&] [and] [chewing lice] [and] [mosquitoes]]
- [Kills [fleas], [ticks], [mosquitoes] and [chewing lice]]
- [Monthly [flea], [tick], [mosquito], and [chewing lice] [treatment]]
- [[Four] [Three] [4] [3] [-]way [action] [control] [kills [fleas], [ticks] [, mosquitoes,] [chewing lice]]
- [[4-Week] [1-month] [30-day] [flea] [and] [&] [tick] treatment]
- [[Four [4] [-] Week] [1-month] [flea], [tick], [mosquito], [and] [&] [chewing lice] control]

- [Kills [fleas] and [ticks] for up to [[4] [four] weeks] [1 month] [30 days]!]
- [Once-a-month [flea] and [tick] treatment]
- [Use [Parastar™] monthly to control [ticks] and [chewing lice]]
- [Use [Parastar™] monthly to control [fleas], [ticks] and [chewing lice]]
- [Monthly [flea], [tick], [mosquito], [and] [&] [chewing] [lice].]
- [Parastar™] provides convenient and effective [flea], [tick] [,] [&] [and] [chewing lice] [and mosquito] control for dogs and puppies 8 weeks and older.]

All Others

- [For dogs and puppies [more than 8 weeks old]]
- [For dogs and puppies [8 weeks old and older]]
- [For dogs [up to 22 lbs], [23 [-] [to] 44 lbs], [45[-] [to] 88 lbs], [89 [-] [to] 132 lbs]]
- [Fast-acting] [Fast acting]
- [Long-lasting] [Long lasting]
- [Prevents [flea] reinfestation of listed pests for [1 month] [4 weeks]]
- [Stops and prevents infestation of listed pests for [4 weeks][1 month]]
- [Stops existing infestation and prevents establishment of additional infestation of listed pests]
- [Convenient spot treatment]
- [Once-a-month treatment]
- [A once monthly application for chewing lice.]
- [Fast action against chewing lice infestations]
- [Controls mites that may cause sarcoptic mange]
- [Three Applications] and/or [3-month supply] or [12-week supply] or [3 applications]
- [Best if used year round!]
- [4[-]week dose[!]] [in Child Resistant Packaging]
- [1[-]month dose[!]] [in Child Resistant Packaging]
- [30[-]day dose[!]] [in Child Resistant Packaging]
- [A fipronil product]
- [fipronil (9.7%)]
- [Contains fipronil[,] [-] the active ingredient used in Frontline® Top Spot®*]
- [*Parastar™ is not manufactured by or distributed by Merial. Frontline® Top Spot® is a registered trademark of Merial.]
- [Specially formulated for dogs and puppies older than 8 weeks]
- [Fast-acting, long-lasting that's also waterproof.]
- [3 Easy-to-Use Applications!] [in Child Resistant Packaging]
- [Easy-to-use [application]]
- [[Free] calendar stickers inside!]
- [[Free] calendar stickers inside]
- [Apply once every [4 weeks] [month] [30 days]!]
- [Waterproof]
- [Dogs can be bathed 24 hours after [application] [treatment] [Parastar™] is applied]]
- [Can be used on breeding, pregnant and lactating [dogs] [bitches] [female dogs]]



- [[Free with purchase] [Free inside] Monthly Application Reminder [Magnet] [clip]
- [card] [inside]]
- [Can be used on puppies [more than 8 weeks of age]
- [Can be used on puppies [8 weeks of age and older]
- [Monthly application reminder card inside]
- [Optional graphics: Images of the different kinds of bugs killed with a line drawn through]

[For Dogs & Puppies 8 weeks or older and] [up to 22 lbs.]

[For Dogs 23[-] [to] 44 lbs.]

[For Dogs 45[-] [to] 88 lbs.]

[For Dogs 89[-] [to] 132 lbs.]

EPA Reg. No. 70585-12

EPA Establishment No.

ACTIVE INGREDIENTS:

Fipronil 9.7 %

INERT INGREDIENTS: 90.3%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back][or][Side][or][Interior Panel][Label Panel[s] for Additional Precautionary Statements [and First Aid Statements]

NET CONTENTS:

[Contains] [Three] [3] [-] 0.023 fl oz (0.67 ml) applicators

[Contains] [Three] [3] [-] 0.045 fl oz (1.34 ml) applicators

[Contains] [Three] [3] [-] 0.091 fl oz (2.68 ml) applicators

[Contains] [Three] [3] [-] 0.136 fl oz (4.02 ml) applicators

Parastar™ 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.

Parastar™ 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.]

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. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs.

FIRST AID	
If swallowed	Call a poison control center for 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 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 1-800-637-0281.	

DIRECTIONS FOR USE

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

Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

Do not use on puppies under 8 weeks of age. [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. Consult a veterinarian before using this product on debilitated, aged, or medicated dogs. Can be used on breeding, pregnant, or lactating dogs. Consult a veterinarian before using on dogs with known organ dysfunction. Dogs may experience some temporary irritation at the site of product application. Certain medications can interact with pesticides. Sensitivities may occur after using ANY pesticide product on dogs. If signs of sensitivity occur bathe your dog with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

[[Outer Packaging or Interior Carton Panel]]

How to open: Remove product [tubes] [vials] from the package. Separate one tube from the others. Holding the [tube] [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

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™ [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. Only one applicator per treatment is needed. 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™ monthly for control of [flea], [tick] [and] [chewing lice] [and mosquito] infestations. [Studies show that] Parastar™ kills fleas for up to three months. If your pet 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™ kills mosquitoes within 24 hours for up to the first 7 days after treatment, then within 48 hours for up to 28 days.] Parastar™ remains effective, after water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. [Dogs can be bathed 24 hours after treatment] Do not reapply for 30 days.

For Dogs Weighing up to 22 lbs. [including small dogs and puppies, 8 weeks or older]:

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

Apply one tube (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 Dogs Weighing 23 [-] [to] 44 lbs.

{For cartons containing 1.34 mL (0.045 fl. oz.) applicator tube}

Apply one tube (1.34 mL) (0.045 fl. oz.) [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 Dogs Weighing 45[-] [to] 88 lbs.

{For cartons containing 2.68 mL (0.091 fl. oz.) applicator tube}

Apply one tube (2.68 mL) (0.091 fl. oz.) [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 Dogs Weighing 89[-] [to] 132 lbs

For cartons containing 4.02 mL (0.136 fl. oz.) applicator tube}

Apply one tube (4.02 mL) (0.136 fl. oz.) [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 and disposal

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: 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.

[Optional Exterior or Interior package copy]

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 NOVARTIS ANIMAL HEALTH US, Inc. (NAHUS) or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold NAHUS and Seller harmless for any claims relating to such factors.

NAHUS 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 NAHUS, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NAHUS 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 NAHUS 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 NAHUS 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 NAHUS OR SELLER, THE REPLACEMENT OF THE PRODUCT.

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

For Technical Information, call: 1-800-637-0281 [hours of service]
[Made in USA]

Distributed by [Manufactured for][Available exclusively from]:
Novartis Animal Health US, Inc.
3200 Northline Avenue, Suite 300
Greensboro NC 27408

[BAR CODE AREA]

EPA Reg. No. 70585-12
EPA Est. NO. XXXXX-XX-XXX

[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:

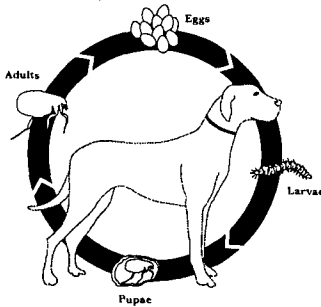
1. Remove product [tubes] [vials] from the package.
2. Separate one [tube] [vial] from the others. Holding the [tube] [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

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]

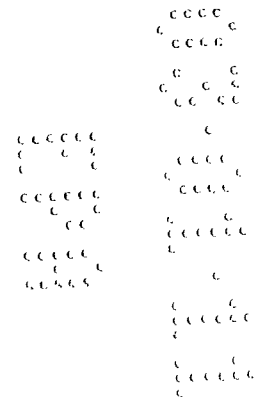
Flea Life Cycle



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

[[Easy] [6] [Six-] [Step] [Parastar™] [Spot-on] [Squeeze-On] Checklist

1. Read the label completely and follow directions.
2. Weigh your pet.
3. Do NOT use dog products on cats.
4. Do NOT treat with more than one pesticide product at a time.
5. Separate animals after treatment to avoid chance of ingestion.
6. Do NOT split tubes between pets.]



[Parastar™]

[Monthly reminder card] [Fill out this reminder card with your pet's name and the date each treatment should be given to your pet as a reminder to reapply [Parastar™] every 30 days.]

[optional graphics that may or may not appear on label]

[Apply [Parastar™] monthly.]

[Pet'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)]

[Visit [web-address] to download a free convenient application for your smartphone for an electronic calendar reminder]

[Visit [web-address] to download a convenient electronic calendar reminder]

[calendar stickers with Parastar™]

[3-month] [application tracker]

[Apply Parastar™ monthly. Place stickers on your calendar as a reminder to reapply [Parastar™] in 30 days.]

[It's time for Parastar™] [!]

[Enclosed for your convenience are [3] [three] stickers.] [Place stickers on your calendar every 30 day from initial treatment as a reminder to reapply Parastar™ every 30 days.]

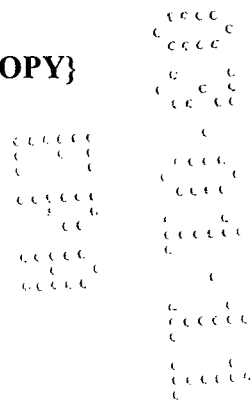
[Optional Example graphics for calendar stickers, reminder cards, and/or magnets.]



[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™. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

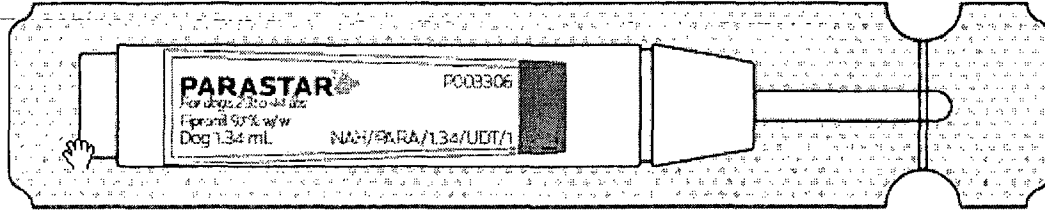
{END - OPTIONAL EXTERIOR OR INTERIOR PANEL PACKAGE COPY}



12
12

[BEGIN TUBE LABEL]

[FRONT OF TUBE]



[Tube contents and dog weight may vary as below:]

For dogs [up to X][X to Y] lbs

Dog 0.67 mL (or) 1.34 mL (or) 2.68 mL (or) 4.02 mL

[Label code may vary]

[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

{label code}

[END TUBE LABEL]

[OPTIONAL GRAPHICS FOR EXTERIOR OR INTERIOR PANEL PACKAGE:

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

