

70585-13

04/29/2011

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 29, 2011

Mr. Ross Gilbert
Agent for Novartis Animal Health US, Inc.
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Subject: Notification to "Change primary band name to 'Parastar Plus'; Change 'pet' and 'pets' to 'dog' and 'dogs' in DFU; and update Storage and Disposal Language "

Product Name: NAH 3
EPA Registration No.: 70585-13
Date of Applications: January 25 and 26, 2011

Dear Mr. Gilbert:

The Agency is in receipt of your above referenced applications for Pesticide Notification under Pesticide Registration (PR) Notice 98-10, for the subject product. The Registration Division (RD), after conducting a review of each request for its applicability, finds that the actions requested fall within the scope of the aforementioned PR Notice.

Please note that we have approved the amended labeling for this product with the understanding that it is consistent with the Agency's previously stamped accepted label(s); and other than the above stated, no other changes have been made to the labeling and/or the Confidential Statement of Formula (CSF).

The label submitted with each application has been stamped "Notification" and will be placed in our records. If you have any questions regarding this letter, please contact Dr. B. A. Akinlosotu at (703) 605-0653.

Sincerely,

Richard Gebken
Richard Gebken,
Product Manager 10
Insecticide Branch
Registration Division (7505P)



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70585-13	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. / NAH 3	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

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

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

Notification of a change in primary brand name per PR Notice 98-10. The new primary brand name is "Parastar Plus™". 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 (email) Ross@PyxisRC.com or (phone) 253-853-7369.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.67, 1.34, 2.68, 4.02 ml.	No. per container 3	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.01, 4.02, 8.04, 12.06 ml.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> 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
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.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ross Gilbert	5. Date 1/25/2011	

[CARTON LABEL - MASTER LABEL COPY]

Parastar Plus™

NOTIFICATION

APR 29 2011

[Apply to puppies over 12 weeks old]
[Apply to puppies 12 weeks or older]

[Mosquitoes]

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

[Adult Fleas]

- [• Kills adult fleas]
- [• Kills newly emerged adult fleas before they lay eggs]
- [• Kills fleas, which may be a source of flea allergy dermatitis] [or, flea bite anemia]
- [• Kills fleas]
- [• Kills fleas Up to [4 weeks] [1 month] [30 days]!]
- [• If dog is at high risk of flea reinfestation, apply once a month]

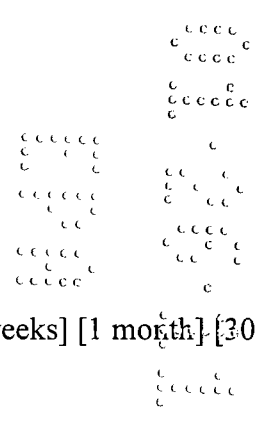
[Multiple Bugs]

- [• Kills chewing lice and controls mites that may cause sarcoptic mange]
- [• Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 12 weeks old and older]
- [• Kills Fleas, Ticks [and] chewing lice [&] [and] [mosquitoes]
- [• Kills Fleas, Ticks [and kills Mosquitoes]
- [• Kills [and] Fleas, Ticks, [and kills chewing lice] [and] [mosquitoes]
- [• Monthly flea, tick, mosquito, and lice application]
- [Kills Fleas, Ticks, mosquitoes, and lice]]
- [• [4 Week] [1 month] [30 day] [Flea and Tick Application]
- [• [Four (4) Week] [1 month] [30 day] [Flea, Tick, Mosquito and Lice Application]
- [• Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]
- [Once A Month Flea and Tick Application]
- [• Use Parastar Plus™ monthly to control Ticks and chewing lice]
- [• Monthly flea, tick, mosquito, and chewing lice protection.]

- [• Flea & Tick Control for Dogs & Puppies 12 weeks old and older]
- [• Kills Fleas, Ticks, and kills chewing lice & mosquitoes]

[Ticks]

- [• Kills Ticks including those that may transmit Lyme disease]
- [• Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
- [• Kills] Deer Ticks [that may transmit Lyme Disease,] for up to [4 weeks] [1 month] [30 days]]
- [• Kills Ticks]
- [• Kills Deer Ticks for up to [4 weeks] [1 month] [30 days]]
- [• Kills [Brown Dog Ticks], [American Dog Ticks,] [and Lone Star Ticks]
- [([Rhipicephalus sanguineus]) for up to [4 weeks] [1 month] [30 days]]
- [• Kills [Brown Dog Ticks], [(Rhipicephalus sanguineus)] for up to [4 weeks] [1 month]



[30 days]]

[• Kills American Dog Ticks [and] [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

[All Others]

[•For Dogs and Puppies 12 weeks of age or older]

[•For Dogs [up to 22 lbs], [23-44 lbs], [45-88 lbs], [89-132 lbs]

[•Fast Acting]

[•Dogs can be bathed 24 hours after application]

[•Long Lasting]

[•Convenient spot application]

[•Fast Action against chewing lice infestations]

[•Controls mites that may cause Sarcoptic Mange]

[• Three Applications] and/or [3 Month Supply] or [12 Week Supply]

[• Best if used year round!]

[• (ICON Showing 4 Week Protection)]

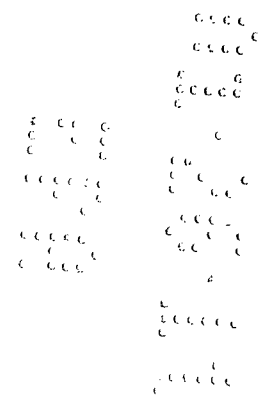
[• 4 Week Dose!]

[• 1 Month Dose!]

[• Easy to Use [Application]]

[• Specially Formulated for Dogs and Puppies]

[• [Free] Calendar Stickers Inside!]



- [• [Free] Calendar Stickers Inside]
- [• Apply once every [4 weeks] [month] [30 days]!]
- [• Dogs can be bathed 24 hours after squeeze-on is applied]
- [• Waterproof]
- [• Can be used on puppies 12 weeks of age and older]
- [• Monthly application reminder card inside]

[For Dogs & Puppies] [12 weeks or older] [and] [up to] 22 lbs.]
 [For Dogs 23-44 lbs.]
 [For Dogs 45-88 lbs.]
 [For Dogs 89-132 lbs.]

[] - Denotes Optional Statements and/or Images that May be Used on Front, Back or Side Label Panels

EPA Reg. No. 70585-13
 EPA Establishment No.

ACTIVE INGREDIENTS:

Fipronil.....	9.8%
Cyphenothrin.....	5.2%
OTHER INGREDIENTS:	<u>85.0%</u>
TOTAL:	100.0%

**KEEP OUT OF REACH OF CHILDREN
 WARNING**

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

NET CONTENTS:

- Contains (3) 0.023 fl oz (0.67 ml) applicators
- Contains (3) 0.045 fl oz (1.34 ml) applicators
- Contains (3) 0.091 fl oz (2.68 ml) applicators
- Contains (3) 0.136 fl oz (4.02 ml) applicators

[BACK/SIDE CARTON LABEL - MASTER LABEL]

Parastar Plus™ contains Fipronil and Cyphenothrin to effectively kill Fleas, Ticks [(including those that may transmit Lyme Disease)], and kills mosquitoes and (chewing) lice. [The active ingredients in Parastar Plus™ work by collecting in the hair follicles and skin oils. 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 30 days on dogs.]

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES OVER 12 WEEKS OF AGE.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS. WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. 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.

FIRST AID	
If In Eyes	<ul style="list-style-type: none"> • 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.
If On Skin Or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none"> • 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.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-637-0281.	
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. READ ENTIRE LABEL [AND ENCLOSED DIRECTIONS] BEFORE EACH USE.

DO NOT USE ON CATS. May be toxic and potentially fatal if applied to or ingested by cats. FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 12 weeks of age. Weigh your dog to be sure you are applying the right dose formulated for the weight of your pet. Do not treat your pet with more than one pesticide product at a time. Over dosing your animal can result in serious illness and even death. **Best if used year round.** Certain medications can interact with pesticides. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. DO NOT USE ON CATS or animals other than dogs. Separate the treated dog from all other dogs and cats for 24 hours after application. Cats and dogs that actively groom or engage in close physical contact with treated dog may be at risk of serious harmful effects. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur immediately feed your dog and continue to monitor your pet for the next 24 hours. If symptoms persist call 1-800-637-0281 to talk to a veterinarian. Cats exhibiting these same symptoms from ingestion should be taken to the veterinarian immediately. If your dog is exhibiting signs of and/or are being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

Sensitivities may occur after using ANY pesticide product on pets. 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 by calling 1-800-637-0281.

[{Outer Packaging }]

How to open: Remove product tubes [vial] 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: Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Repeat application may be made if necessary, but do not apply more often than once every 30 days.

FREQUENCY OF APPLICATION

Use Parastar Plus™ monthly for complete control of flea, tick [and] chewing lice [and to kill mosquitoes] [infestations]. [[Studies show that] Parastar Plus™ kills fleas for up to 30 days]. If your pet is at high risk of flea reinfestation [, or in a highly infested environment], apply monthly. Apply monthly to control ticks, mosquitoes and chewing lice. Parastar Plus™ kills mosquitoes within 24 hours for up to the first 7 days after application, then within 48 hours for up to 28 days. Parastar Plus™ remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

For Dogs Weighing up to 22 lbs.

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

Apply one tube (.67ml)(0.023 fl. oz.) [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].

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For Dogs Weighing Between 23 and 44 lbs.

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

[Apply one tube (1.34 ml)(0.045 fl. oz.)] [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].

For Dogs Weighing Between 45-88lbs.

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

Apply one tube (2.68 ml)(0.091 fl. oz.) [as a spot on the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

For Dogs Weighing 89-132 lbs

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

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

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.

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: Novartis Animal Health US, Inc., (address).]

In Case of Emergency, call: 1-800-637-0281 [For more information]
Non-Emergency call (number) [Made in USA]

Distributed by:
Novartis Animal Health US, Inc.
3200 Northline Avenue, Suite 300
Greensboro NC 27408

[BAR CODE AREA]

EPA Reg. No. 70585-13
EPA Est. No. XXXXX-XX-XXX

[Package copy]

[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.]

[{Outer Packaging}]

How to open

1. Remove product tubes [vial] from the package.
2. 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:

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

**[Flea life cycle diagram]
[diagram with visual of fipronil collecting and being released from hair follicle]**

[Look at the Label (Look at the Label icon) 6 Step [Easy] [Parastar Plus™] [Spot On] [Squeeze-On] Checklist

- Read the label completely and follow directions
- Weigh your pet
- Do NOT use Dog products on Cats
- Do NOT treat with more than one pesticide product at a time
- Separate animals after application to avoid chance of ingestion

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- Do NOT split tubes between pets]

Parastar Plus™

[Monthly reminder card]

[Apply Parastar Plus™ monthly for continuous protection against Fleas, Ticks, [and] chewing lice [and mosquitoes].]

[Pet's Name (Empty blank for owner to fill in name)]

[First [dose] [Application] (Empty blank for owner to fill in date)]

[Second [dose] [Application] (Empty blank for owner to fill in date)]

[Third [dose] [Application] (Empty blank for owner to fill in date)]

[calendar stickers with brand name] [Place stickers on your calendar as a reminder to reapply

[brand name] [in 30 days.]

{END - BACK / SIDE PANEL}

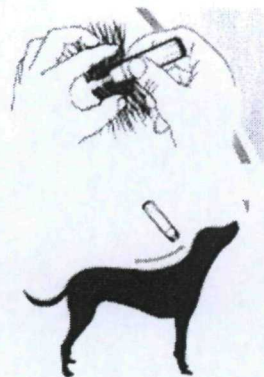
TUBE / VIAL LABEL

Front Label

Back Label

<p>Parastar Plus™ Fipronil 9.8%, Cyphenothrin 5.2% Dog 0.67 mL (or) 1.34 mL (or) 2.68 mL (or) 4.02 mL {label code}</p>	<p>KEEP OUT OF REACH OF CHILDREN WARNING: Read directions and precautions before using. Use scissors to open. EPA REG. No. 70585-13 {label code}</p>
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[Optional: Example pictograms that may or may not be found on the printed label]



EPA 20110114