

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7504P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460 EPA Registration No.

Date of Issuance:

70585-12

January 28, 2011

NOTICE OF PESTICIDE:

☑ Registration☐ Reregistration

(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

Term of Issuance:

Conditional Registration

Time-limited: see conditions below

Name of Pesticide Product:

NAH 2

Name and Address of Registrant (include ZIP Code):

Novartis Animal Health (c/o Pyxis Regulatory Consulting, Inc.) 3200 Northline Avenue, Suite 300 Greensboro, NC 27408

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA §3(c)(7)(a) provided that:

- 1. This registration is time-limited and expires two years from the date this product is first released for shipment.
 - You must provide the Agency with a projected release for shipment date within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.
- 2. Consider limiting the formulations of each product to one basic confidential statement of formula, if applicable. The Agency may require this in the future. It is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
- 3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on April 1, 2011. The quarterly reports are due two months after each quarter ends.

Please flag any Confidential Business Information as such. Enhanced incident reporting should

be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #
Where purchased: internet, store, veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify) Breed: (as reported by pet owner)

Age: months or years Sex: M, F, or neutered Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other Body System: neurological, dermatological, GI, respiratory, ocular, other

Major signs noted with separate column for each sign, using standard terminology

Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor Outcome: died, recovered, still treated, unknown

- 4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).

- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.
- 5. You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under FIFRA section 4.

All labeling comments below are in reference to the proposed master label, dated January 17, 2011. These comments apply to all submitted draft labeling, including the master label, the color mock-up labels, and the proposed text and graphics for the stickers and magnet:

- 6. On page 1 under Mosquitoes, revise the claims (delete struck-out text and/or add underlined words) to read as follows:
 - "[[Kills mosquitoes] [within 24 hours] [within 24 hours for <u>up to</u> the first 7 days after treatment, and within 48 hours for up to 28 days]]."
- 7. On page 1 under Adult Fleas, delete revise the claims (delete struck-out text and/or add underlined words) to read as follows:
 - "[Kills fleas, a source of flea allergy dermatitis] [, flea bite anemia] [and] [, tapeworm infestations]"
 - "[If dog is a high risk for flea reinfestation, apply once a month application may be needed]"
- 8. On page 1 under Ticks, revise the claims (delete struck-out text and/or add underlined words) to read as follows:
 - "Kills [and] [repels] ticks for up to [[4] [four] weeks [1 month] [30 days]!]"
 - "[Kills-[all stages of] deer ticks [that may transmit Lyme disease,] [before they can transmit Lyme disease] for up to [[4] [four] weeks] [1 months] [30 days]"
 - "[Kills ticks [before they can transmit disease]]"

- 9. On pages 1 and 2 under Multiple Infestations, revise the claims (delete struck-out text and/or add underlined words) to read as follows:
 - "Monthly [flea], [tick], [mosquito], and [chewing lice] [protection] [treatment]"
 - "[Four] [Three] [4] [3] Way [Action] [Control] Protection, [kills [fleas], [ticks], [mosquitoes], [chewing lice]]"
 - "[Four (4) [-] Week] [1 month] [30 day] [Flea], [Tick], [Mosquito], [and] [&] [Chewing Lice] control]"
 - "[Monthly [flea], [tick], [mosquito] [and] [&] [chewing lice] protection.]"
 - "NAH 1 provides [convenient] and [effective] [flea], [tick] [,] [&] [and] [chewing lice] [and mosquito] control for dogs and puppies 8 weeks and older.]"
- 10. On pages 2 and 3 under All Others, revise the claims (delete struck-out text and/or add underlined words) to read as follows:
 - "[For dogs and puppies [8 weeks old and older] [more than 8 weeks old]]"
 - "[For dogs and puppies [8 weeks old and older] [more than 8 weeks old]]"
 - "[Once-a-month treatment recommended]"
 - "[A once monthly application is recommended for chewing lice]"
 - "[Three applications {for cartons with 3 applicators}] and/or [3-month supply] or [12-week supply] or [f3] applications]"
 - "[(Icon showing 4-week protection)]"
 - "[Fast-acting, long-lasting protection that's also waterproof.]"
 - "[[Free] brochure inside!]"
 - "[[Free] brochure and calendar stickers inside]"
 - "[Can be used on puppies [8 weeks of age and older] [more than 8 weeks of age]]"
 - "[Can be used on puppies [8 weeks of age and older] [more than 8 weeks of age]]"
- 11. On page 3 under the Caution, delete "[or] [insert]" because this has not been submitted to the Agency for review and approval.
- 12. On page 3 below the Net Contents, replace "30 days" from the second claim with "[1 month] [4 weeks]" because the data does not support mosquito control for up to 30 days.
- 13. On page 3 under Read Entire Label Before Each Use, delete "[before they can transmit disease]."
- 14. On page 4, delete "[and enclosed directions]" from the Directions for Use because this insert has not been submitted to the Agency for review.
- 15. On page 5, delete the reference to the "insert diagram that depicts application of product on the dog" because this has not been submitted to the Agency for review.
- 16. On page 5 under the How to Apply instructions continued from page 4, replace "[4] [four] weeks" with "30 days" to be consistent with the Frequency of Application information.
- 17. On page 5 under Frequency of Application, revise the fourth statement to read as follows:
 - "NAH 1 kills mosquitoes within 24 hours for <u>up to</u> the first 7 days after treatment, then within 48 hours for up to 28 days.]"
- 18. On pages 6 and 9, delete "insert copy" because this insert has not been submitted to the Agency

for review.

- 19. With respect to referenced optional web-address additions to the product label, please be advised that referenced web pages or URLs associated with this product are also subject to review and approval by the Agency.
- 20. On page 8, delete "protection" from the various claims.
- 21. On page 8, delete "Actual graphics may differ slightly" from the Optional Example Graphics claim, as this must be submitted to the Agency for review and approval prior to production.
- 22. On page 9, delete the graphics that show the person's arms cutting the package, or applying the product on the dog's back because these images were not originally submitted for approval when the Agency completed their review for child-resistant packaging.
- 23. Be advised that regarding the text to be printed on the front of the tube, the net weight must be expressed in English units, i.e., "0.017 fl oz." Metric units may be expressed in addition to (adjacent) to the English unit weight expression.
- 24. Revise the EPA Registration Number to read: "EPA Registration No. 70585-12."

If the Agency determines that future mitigation measures are necessary for all pet spot-on products, you will be informed, and be expected to comply. If mitigation measures are necessary, the Agency may take appropriate regulatory actions. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please contact Rosanna Louie-Juzwiak at (703) 308-0037 with any questions.

Enclosure: NAH 2 Label, Stamped Accepted with Comments

Signature of Approving Official:

JAN 2 8 2011

Richard Gebken, Product Manager (10)

Registration Division, Insecticide Branch

EPA Form 8570-6

[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 or on package insert]

NAH 2 [Alternate Brand Name: ParastarTM]

ACCEPTED with COMMENTS In EPA Letter Dated:

JAN 28 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 70585-12

[Apply to puppies more than 8 weeks old] [Apply to puppies 8 weeks or older]

[Mosquitoes]

• [[Kills mosquitoes] [within 24 hours] [within 24 hours for 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] [and] [, tapeworm infestations]
- [Kills fleas [for] up to [4 weeks] [1 month] [30 days] [!]]
- [If dog is a high risk for flea reinfestation a once-a-month application may be needed]

[Ticks]

- [Kills ticks, including those that may transmit Lyme disease]
- [Kills [and] [repels] ticks for up to [[4] [four] weeks] [1 month] [30 days]!]
- [Kills [all stages of] deer ticks [that may transmit Lyme disease,] [before they can transmit Lyme disease] for up to [[4] [four] weeks] [l month] [30 days]]
- [Kills ticks (including deer ticks) for up to [[4] [four] weeks] [l month] [30 days]]
- [Kills [brown dog ticks], [American dog ticks,] [and lone star ticks]
- [Kills ticks [before they can transmit disease]]
- [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] [protection] [treatment]]
- [[Four] [Three] [4] [3] [-]way protection [kills [fleas], [ticks] [, mosquitoes,] and [lice]]
- [[4-Week] [1-month] [30-day] [flea] [and] [&] [tick] treatment]

- [[Four [4] [-] Week] [l-month] [30-day] [flea], [tick], [mosquito], [and] [&] [lice] control]
- [Kills [fleas] and [ticks] for up to [[4] [four] weeks] [1 month] [30 days]!]
- [Once-a-month [flea] and [tick] treatment]
- [Use [NAH 2] monthly to control [ticks] and [chewing lice]]
- [Use [NAH 2] monthly to control [fleas], [ticks] and [chewing lice]]
- [Monthly [flea], [tick], [mosquito], [and] [&] [chewing] [lice] protection.]
- [NAH 2] provides convenient and effective [flea], [tick] [,] [&] [and] [chewing lice] [and mosquito] control for dogs and puppies 8 weeks of age or older.]

All Others

- [For dogs and puppies [8 weeks of age or older] [more than 8 weeks old]]
- [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 recommended]
- [A once monthly application is recommended for chewing lice.]
- [Fast action against chewing lice infestations]
- [Controls mites that may cause sarcoptic mange]
- [Three Applications {for cartons with 3 applicators}] and/or [3-month supply] or [12-week supply] or [[3] applications]
- [Best if used year round!]
- [(Icon showing 4-week protection)]
- [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®*
- [*NAH 2 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 protection that's also waterproof.]
- [3 Easy-to-Use Applications!] [in Child Resistant Packaging]
- [Easy-to-use [application]]
- [[Free] calendar stickers inside!]
- [[Free] brochure inside!]
- [[Free] brochure and calendar stickers inside]
- [Apply once every [4 weeks] [month] [30 days]!]

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- [Waterproof]
- [Dogs can be bathed 24 hours after [application] [treatment] [NAH 2] 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 [8 weeks of age and older] [more than 8 weeks of age]
- [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-XX

EPA Establishment No.

ACTIVE INGREDIENTS:

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

KEEP OUT OF REACH OF CHILDREN CAUTION

See [Back][or][Side][or][Interior Panel][Label Panel[s] [or] [insert] 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

NAH 2 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 30 days on dogs].

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.

NAH 2 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] [before they can transmit 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 [AND ENCLOSED DIRECTIONS] 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.

[(INSERT DIAGRAM THAT DEPICTS APPLICATION OF PRODUCT ON THE DOG]

[{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 NAH 2 [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 [4] [four] weeks.

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

FREQUENCY OF APPLICATION

Use NAH 2 monthly for control of [flea], [tick] [and] [chewing lice] [and mosquito] infestations. [Studies show that] NAH 2 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]. NAH 2 kills mosquitoes within 24 hours for the first 7 days after treatment, then within 48 hours for up to 28 days.] NAH 2 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 Insert or 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-XX EPA Est. NO. XXXXX-XXXX

[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.]

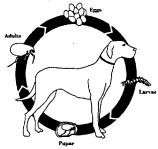
How to Open:

- 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]



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

[[Easy] [6] [Six-] [Step] [NAH 2] [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.]

[NAH 2]

[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 [NAH 2] every 30 days.] [optional graphics that may or may not appear on label]

[For year round protection apply [NAH 2] 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 [dosē] [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 NAH 2]

[3-month] [application tracker]

[For year-round protection, apply NAH 2 monthly. Place stickers on your calendar as a reminder to reapply [NAH 2] in 30 days.]

[It's time for NAH 2] [!]]

[Enclosed for your convenience are [3] [three] stickers.] [Place stickers on your calendar every 30 day from initial treatment as a reminder to reapply NAH 2 every 30 days.]

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



[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 NAH 2. 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 INSERT OR EXTERIOR OR INTERIOR PANEL PACKAGE COPY}

Front Label

NAH 2

[cat graphic with line through]

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

Fipronil 9.7% w/w

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

4.02 mL {label code}

Back Label

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read accompanying directions

and precautions before using. Use scissors to

open.

EPA REG. No. 70585-XX

{label code}

JOPTIONAL GRAPHICS FOR INSERT OR EXTERIOR OR INTERIOR PANEL

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











DO NOT

