

AUG 18 2005

Jerry Alperin
Farnam Companies, Inc.
301 West Osborn
Phoenix, AZ 85013

Subject: Proposed Additional Efficacy Claim For:
Farnum Purge Plus Insecticide
EPA Registration No. 270-278
Application dated March 11, 2005

Dear Mr. Alperin:

The data submitted support the claim of blood-feeding inhibition by the Asian tiger mosquito, *Aedes albopictus*. The Asian tiger mosquito naturally feeds on dogs and is an important vector of canine heartworm, *Dirofilaria immitis*. However, susceptibility of dogs to illness associated with West Nile virus infection is not established. Neither are dogs confirmed to exhibit clinical symptoms of West Nile virus (WNV); although they may become infected with WNV. Furthermore, dogs have not been found to function as intermediate hosts of the virus, resulting in subsequent transmission to humans or other susceptible hosts.

At this time, there is insufficient evidence (i.e., clinically recognizable presentation of symptoms) to support the inclusion of claims that refer to protection of dogs from vectors of WNV. Should demonstrable evidence of dog susceptibility become generally recognized within the veterinary community, this proposed amendment may be revisited.

The data submitted generally substantiate the suitability of this product for use against vectors of canine heartworm.

The proposed label is being accepted subject to the following comments:

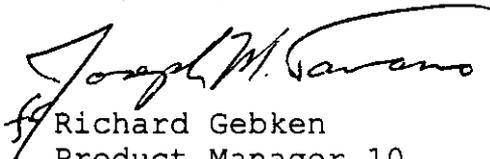
- 1) Delete the claim, "Repels mosquito(es) [(vectors of) (which may transmit) West Nile Virus]."
- 2) Delete the claim, "Protects against blood feeding by mosquito(es) [(vectors of) (which may carry) (which may transmit) West Nile Virus]."
- 3) Delete the claim, "(Inhibits) (reduces) (prevents) blood feeding by mosquito(es) [(vectors of) (which may carry) (which may transmit) West Nile Virus]."

Submit five copies of revised labeling corrected in accordance with the comment listed above.

A copy of the Efficacy review is enclosed for your information

If you have any questions please contact Joseph Tavano at (703) 305-6411.

Sincerely,



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



**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

AUG 18 2005

(Front) Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 270-278 **ARNAM PURGE PLUS INSECTICIDE**



**PLEASANT CITRUS SCENT
FLEA & TICK CONTROL FOR DOGS AND PUPPIES OVER 12 WEEKS OF AGE**

FOR DOGS [15 lbs and Under][Between 15 & 33 lbs][Between 33 & 66 lbs][66 lbs & Over]

DO NOT USE ON CATS

- BREAKS FLEA LIFE CYCLE!
- KILLS & REPELS FLEAS UP TO 3 TO 4 WEEKS!
- KILLS FLEA EGGS AND LARVAE FOR UP TO 123 DAYS!
- PREVENTS FLEA EGGS FROM DEVELOPING INTO BITING ADULTS FOR UP TO 123 DAYS!
- KILLS AND REPELS MOSQUITOES!
- PROTECTS AGAINST BLOOD FEEDING BY MOSQUITOES (CARRIER of HEARTWORM) UP TO 4 WEEKS!
- KILLS & REPELS TICKS FOR UP TO 4 WEEKS!
- KILLS & REPELS DEER TICKS (CARRIER of LYME DISEASE) FOR UP TO 4 WEEKS!
- KILLS & REPELS BROWN DOG TICKS (Rhipicephalus sanguineus) FOR UP TO 3 TO 4 WEEKS!
- KILLS & REPELS AMERICAN DOG TICKS (Dermacentor variabilis) FOR UP TO 3 TO 4 WEEKS!
- MONTHLY APPLICATION
- MONTHLY FLEA, TICK AND MOSQUITO TREATMENT!
- KILLS AND REPELS FLEAS AND TICKS FOR UP TO A MONTH!
- KILLS AND REPELS ADULT FLEAS FOR UP TO 3 TO 4 WEEKS!
- KILLS FLEA EGGS AND LARVAE [FOR UP TO 4 MONTHS][FOR 123 DAYS]!
- KILLS AND REPELS TICKS FOR UP TO [4 WEEKS][3 TO 4 WEEKS] INCLUDING DEER TICKS (CARRIER of LYME DISEASE), BROWN DOG TICKS & AMERICAN DOG TICKS!
- KILLS AND REPELS [ADULT FLEAS] FOR UP TO 3 TO 4 WEEKS
- PREMIUM PROTECTION FOR LESS!
- Repels mosquito(es) [(vectors of) (which may carry) (which may transmit) West Nile Virus]
- Protects against blood feeding by mosquito(es) [(vectors of) (which may carry) (which may transmit) West Nile Virus]
- (Inhibits) (reduces) (prevents) blood feeding by mosquito(es) [(vectors of) (which may carry) (which may transmit) West Nile Virus]

ACTIVE INGREDIENTS

Permethrin* (CAS #52645-53-1)	45.0%
Pyriproxyfen (CAS #95737-68-1) (Nylar®).....	5.0%
OTHER INGREDIENTS.....	50.0%
TOTAL	100.0%

*Cis/trans ratio: Max 55% (±) cis and min 45% (±) trans

Nylar® is a registered trademark of McLaughlin Gormley King Company

U.S. Patent No. 5,942,525

**KEEP OUT OF REACH OF CHILDREN
CAUTION
DO NOT USE ON CATS
SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS**

EPA Reg. No.: 270-278

EPA Est. No.: XXX-XX-XXX

Net Contents: XX [.03 fl. oz. (1.0 ml)][.05 fl. oz. (1.5 ml)][.1 fl. oz. (3.0 ml)] [4.5 ml]Applicator

(Back)

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS OVER 12 WEEKS OF AGE
DO NOT USE ON CATS**

**FARNAM PURGE PLUS INSECTICIDE
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Hazards to Humans: Harmful if swallowed. Avoid contact with eyes or clothing. Causes moderate eye irritation. Wash thoroughly with soap and water after handling.

Hazards to Domestic Animals: **FOR EXTERNAL USE ON DOGS ONLY.** Do not use on puppies under 12 weeks of age. 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. Cats which actively groom or engage in close physical contact with treated dogs may be at risk of serious harmful effect. Certain medications can interact with pesticides. It is advisable to consult a veterinarian before using this product with any other pesticide or drug.

FIRST AID	
IF SWALLOWED	<ol style="list-style-type: none"> 1. Call a poison control center or doctor immediately for treatment advice. 2. Have person sip a glass of water if able to swallow. 3. Do not induce vomiting unless told to do so by the poison control center or doctor. 4. Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ol style="list-style-type: none"> 1. Hold eye open and rinse slowly and gently with water for 15-20 minutes. 2. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. 3. Call a poison control center or doctor for treatment advice.
<p>[HOT LINE NUMBER] [You may contact 1-602-285-1660 for emergency medical treatment information.] [In case of emergency or for product information, call (602) 285-1660, Monday-Friday, 7:00 AM – 3:45 PM MST.]</p>	
<p>Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment.</p>	

Adverse Reactions: Some animals may be sensitive to ingredients in this product. Reactions in dogs may include skin sensitivity. Dogs may show lethargy, increased pruritus (itchiness), erythema (redness), rash and hair discoloration or hair loss at the application site. Observe the dog following treatment. Sensitivity may occur after using ANY pesticide product on pets. If

signs of sensitivity occur bathe your dog with a mild, non-insecticidal shampoo and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

DIRECTIONS FOR USE

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

DO NOT USE ON CATS or animals other than dogs. May be toxic and potentially fatal if applied to or ingested by cats. Do not get this product in your dog's eyes or mouth. Repeat applications may be made if necessary, but do not apply more often than once every 3 weeks, except to reapply after shampooing the dog.

HOW TO APPLY:

1. Remove product tube from package.
2. Holding tube with notched end pointing up and away from face and body, snap or cut off narrow end at notches.
3. Invert tube over dog and use open end to part dog's hair.
4. Squeeze tube firmly to apply all of the solution to the dog's skin.

[For Dogs Weighing 15 lbs and Under (1.0 ml applicator tubes)]

5. Apply one tube (1.0 ml) as a spot or stripe to the dog's back between the shoulder blades.]

[For Dogs Weighing Between 15 and 33 lbs (1.5 ml applicator tubes)]

5. Apply one tube (1.5 ml) as a spot or stripe to the dog's back between the shoulder blades.]

[For Dogs Weighing Between 33 and 66 lbs (1.5 ml applicator tubes)]

5. Apply one tube (1.5 ml) as a spot or stripe to the dog's back between the shoulder blades and apply a second tube (1.5 ml) as a spot or stripe to the dog's back directly in front of the base of the tail.

OR

[(3.0 ml applicator tubes)]

Apply the entire tube (3.0 ml) as a continuous stripe on the dog's back starting between the shoulder blades and ending directly in front of the base of the tail or apply approximately half of the tube (1.5 ml) as a spot or stripe to the dog's back between the shoulder blades and apply the rest of the tube's contents (1.5 ml) as a spot or stripe to the dog's back directly in front of the base of the tail.

[For Dogs Weighing 66 lbs and Over (1.5 ml applicator tubes)]

- 5. Apply one tube (1.5 ml) as a stripe to the dog's back between the shoulder blades and apply a second tube (1.5 ml) continuing the stripe down the center of the dog's back and apply a third tube (1.5 ml) to the dog's back directly in front of the base of the tail.]

OR

[(4.5 ml applicator tube)]

- 5. Apply the entire tube (4.5 ml) as a continuous stripe on the dog's back starting between the shoulder blades and ending directly in front of the base of the tail or apply approximately half of the tube (2.25 ml) as a spot or stripe to the dog's back between the shoulder blades and apply the rest of the tube's contents (2.25 ml) as a spot or stripe to the dog's back directly in front of the base of the tail.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a cool, dry place. Protect from freezing.

Disposal: If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

Never place unused product down any indoor or outdoor drain.

FARNAM PURGE PLUS INSECTICIDE is an effective and easy to use product. FARNAM PURGE PLUS INSECTICIDE has demonstrated greater than 92% control of fleas within one day of application. FARNAM PURGE PLUS INSECTICIDE prevents eggs from fleas on treated dogs from developing into biting adults for up to [4 months][123 days]. As with all flea and tick control products, FARNAM PURGE PLUS INSECTICIDE should be used as part of a program aimed at reducing flea populations in the dog's environment (bedding, carpets, kennel, yard). Consult your veterinarian, entomologist, or retailer for program recommendations.

OR

FARNAM PURGE PLUS INSECTICIDE is an effective and easy to use product. FARNAM PURGE PLUS INSECTICIDE has demonstrated greater than 92% control of fleas within one day of application. FARNAM PURGE PLUS INSECTICIDE prevents eggs from fleas on treated dogs from developing into biting adults for up to [4 months][123 days]. FARNAM PURGE PLUS INSECTICIDE kills and repels Deer Ticks (carrier of Lyme Disease), Brown Dog Ticks, and American Dog Ticks for up to [3 to 4 weeks][4 weeks]. FARNAM PURGE PLUS INSECTICIDE also kills and repels mosquitoes and protects against blood feeding by mosquitoes (carrier of heartworm) for up to 4 weeks.

NOTICE OF WARRANTY

FARNAM COMPANIES, INC. MAKES NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR OTHERWISE, EXPRESSED OR IMPLIED, CONCERNING THIS PRODUCT OR ITS USES WHICH EXTEND BEYOND THE USE OF THE PRODUCT UNDER NORMAL CONDITIONS IN ACCORDANCE WITH THE STATEMENTS MADE ON THIS LABEL.

OPTIONAL LANGUAGE:

HOW TO APPLY:

[FOR SARAN TUBES IN BLISTER CARD:] Remove product tube from package. Holding tube with notched end pointing up and away from face and body, snap or cut off narrow end at notches. 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. Wrap tube and put in trash.

OR

[FOR FLAT CARD (doubled) UNIT-DOSE PACKAGING:] [Separate cards along the perforated line. Holding separated card by its wide end with narrow end pointed up and away from face and body, cut along dotted line. Invert card over dog and use narrow end of the card to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin. Wrap card and put in trash.]

OR

[FOR FLAT CARD UNIT DOSE PACKAGING:] [[For push pin type applicator] Remove one product tube from card. With cap end pointed up and away from face and body, depress cap to pierce tube end. Carefully remove cap, invert tube over dog, and with tube in close to dog's skin, squeeze tube to apply product. Wrap empty tube and put in trash.]

OR

[FOR FOLDING CARD OR TABBED CARD UNIT-DOSE PACKAGING:] [Remove product tab by tearing along perforation. Holding tab with tube end pointed up and away from face and body, cut along dotted line. Invert tab over dog and use narrow end of card to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin.]

OR

[FOR BLISTER CARD WITH TRI-LAYER TUBES:] [Remove product tube(s) from package. Fold along perforation between tubes and tear off one (or more) tube(s). [Return unused tubes to package.] Holding tube with notched end pointing up and away from face and body, snap off [or cut] narrow end at notches. 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.]

[** FOR MULTI-DOSE PACKAGING: Withdraw 1.0 ml (1.5 ml)(3.0 ml)(4.5 ml.) of solution at a time. Apply entire given dose directly to the skin at the indicated locations.]

[** FOR DROPPER BOTTLE MULTI-DOSE PACKAGING: Insert dropper tube into insecticide solution, squeeze bulb and then release to fill tube barrel to 1.0 ml (1.5 ml)(3.0 ml)(4.5 ml.) line. Position dropper tube end in dog's hair next to skin and squeeze bulb to apply all of the solution to the dog's skin as indicated for dog's size.]

[** FOR SALE TO VETERINARIANS ONLY]

Manufactured For: Farnam Companies, Inc.
Phoenix, Arizona 85013-3997

IN CASE OF EMERGENCY CALL:602-285-1660

(lot number statements as needed) Mfg. & Printed in U.S.A. (label revision number) (product #)

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TUBE LABEL (folding card and flat card packaging designs)
FARNAM PURGE PLUS INSECTICIDE



PERMETHRIN 45% W/W
PYRIPROXYFEN 5% W/W

KEEP OUT OF REACH OF CHILDREN
READ DIRECTIONS AND
PRECAUTIONS BEFORE USING

EPA Reg. No. 270-278

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TAB LABEL (folding card and tabbed card packaging designs)

FARNAM PURGE PLUS INSECTICIDE



ACTIVE INGREDIENTS

Permethrin (CAS #52645-53-1)	45.0%
Pyriproxyfen (CAS #95737-68-1) (Nylar®).....	5.0%

KEEP OUT OF REACH OF CHILDREN
SEE MAIN LABEL FOR ADDITIONAL
PRECAUTIONS AND INSTRUCTIONS FOR USE

EPA Reg. No. 270-278

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OUTER BOX LABEL (Contains the following labeling plus full product label)

FARNAM PURGE PLUS INSECTICIDE

BIOLAR (*Nylar) inhibits development of the immature stages of the fleas for up to 4 months preventing them from reaching the biting adult stage.

- Nylar – Registered Trademark of McLaughlin Gormley King and Company

PICTURE OF FLEA LIFE CYCLE HERE

As part of a complete flea control program Use Bio Flea Halt! Outdoor Yard Spray Concentrate and Bio Flea Halt! Carpet Powder or Carpet Spray with Biolar Insect Growth Regulator, along with on-animal flea & tick products.

4 STEPS FOR COMPLETE FLEA CONTROL

- Step 1 – Shampoo or dip your dog.
- Step 2 – Treat indoor and outdoor premise with Bio Flea Halt! indoor and outdoor sprays, foggers and powders.
- Step 3 – Apply Bio Spot-On for up to four weeks' adult flea and tick control.
- Step 4 – Maintenance treatments with on-animal sprays and powders.