

AUG 18 2005

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

Subject: Proposed Additional Efficacy Claim For:
Farnam Pet Spray 549
EPA Registration No. 270-307
Application dated March 11, 2005

Dear Mr. Alperin:

The data submitted support the claim of blood-feeding inhibition and mortality 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 and cats to illness associated with West Nile virus infection is not established. Neither dogs, nor cats, are confirmed to exhibit clinical symptoms of West Nile virus (WNV); although they may become infected with WNV. Furthermore, neither dogs, nor cats have 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 or cats from vectors of WNV. Should demonstrable evidence of dog or cat 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]."
- 4) A claim for use against vectors of canine heartworm may be added to the label for this product.

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)



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

270-307

[] OR () indicates alternate or optional wording

FARNAM PET SPRAY 549

- Contains [Biolar®] an insect growth regulator [IGR]
- Biolar® [brand name] is an insect growth regulator similar to [naturally occurring] insect juvenile hormone, which stops [interferes with] insect growth and development.
- [Biolar®][brand name] stops [prevents] the fleas from developing into [egg laying] adults.
- [Biolar®][brand name] can be used as part of an integrated pest management [IPM] program.
- [Biolar®][brand name] keeps working in areas exposed to the sun.
- [Biolar®][brand name] inhibits reinfestation of fleas for up to 100 days [14 weeks][3 months].
- Kills adult fleas [and ticks].
- Aids in the quick removal of ticks.
- Kills pre-adult fleas, including flea eggs for 100 days [14 weeks][3 months].
- If adult fleas are introduced, their offspring will not become biting [reproductive] adults.
- Prevents larval fleas from developing into the biting adult stage.
- Prevents [stops] hatching fleas [pre-adult (larval) fleas][eggs (hatching eggs)(larvae)] from becoming full grown (developing into) biting adults.
- One treatment works for [100 days] [14 weeks][3 months] against hatching fleas [pre-adult (larval) fleas][eggs (hatching eggs)(larvae)].
- Kills (present) (today's) fleas and prevents (new) (tomorrow's) fleas from developing into the biting adult stage.
- [Biolar®] [brand name] activity keeps working for [100 days] [14 weeks][3 months].
- Prevents [stops] the emergence of [biting][reproductive] adult fleas.
- Flea eggs deposited on the dog [cat][pet] will not develop into adult fleas.
- [Biolar®][brand name] acts on immature [life stages of] fleas, preventing them from developing into biting adults.
- Aids in the control of flea bite dermatitis by killing [controlling] fleas.
- Safe on miniature and toy breeds.
- [Kills] [controls] and Repels: Fleas, Ticks, Lice, Flies, Mosquitoes and Gnats.
- Also [kills] [controls] Deer Ticks and other tick [Ixodid] species that may carry and transmit Lyme Disease.
- Kills on contact, Ticks, Spiders, Ants, Roaches and other listed insects.
- Effective long term control
- Ready-To-Use [RTU] Spray
- Non-Aerosol
- Also kills flea eggs and larvae for 3 months
- Use on cat, cat bed, carpet, furniture
- For use on cats AND areas where cats frequent – Carpets, Upholstery, Pet Bedding
- 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:

Pyriproxyfen 2-[1-methyl-2-(4-phenoxyphenoxy)	
ethoxy] pyridine (Nylar®)	0.125%
Pyrethrins	0.180%
*N-Octyl bicycloheptene dicarboximide	1.000%

OTHER INGREDIENTS:	98.695%
TOTAL	100.000%

*MGK® 264, Insecticide Synergist
Nylar® and MGK® are registered trademarks of McLaughlin Gormley King Company

Keep Out Of Reach Of Children
WARNING
See Side Panel for Additional Precautionary Statements

EPA Reg. No. 270-307

Net Contents _____

EPA Est. No. _____

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[] OR () indicates alternate or optional wording

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY IN A WELL VENTILATED AREA
USE ONLY ON DOGS AND ADULT CATS
DO NOT TREAT DOGS UNDER 6 MONTHS OF AGE WITH THIS PRODUCT
DO NOT TREAT CATS UNDER 7 MONTHS OF AGE WITH THIS PRODUCT**

[Farnam Pet Spray 549][brand name] kills [controls] insects [on contact][such as]:

- | | |
|--|------------------------|
| Fleas [adults (larvae) (eggs) (pre-adult)] | Spiders |
| Ticks [that may carry and transmit Lyme Disease] | Scorpions |
| Brown Dog Ticks | Ants |
| Lone Star Ticks | Flies |
| Deer Tick | Waterbugs |
| Other Ixodid species | Cockroaches |
| American Dog Tick | Smoky Brown Cockroach |
| Gulf Coast Tick | Brown Banded Cockroach |
| Lice | Asian Cockroach |
| Mosquitoes | German Cockroach |
| Sowbugs | American Cockroach |
| Millipedes | Australian Cockroach |
| Beetles | Oriental Cockroach |
| Pillbugs | Crickets |
| Centipedes | Palmetto Bugs |

For use in areas [such as]: Animal Runs, Animal Holding Areas, Animal Quarters, Apartments, Attics, Automobiles, Basements, Bedrooms, Boarding Kennels, Boats, Campers, Cat Beds, Closets, Condominiums, Decks, Dens, Dog Beds, Dog Houses, Dormitories, Floors, Garages, Gazebos, Homes, Hotels, Kennels, Kitchens, Lanais, Living Rooms, Motels, Patios, Pet Bedding, Pet Carriers, Pet Grooming Parlors, Pet Sleeping Areas, Pet Stores, Play Rooms, Porches, Recreational Vehicles, Rooms, Scratching Posts, Utility Rooms, Verandahs, Veterinary Clinics/Hospitals, Zoos.

[Farnam Pet Spray 549] [brand name] for [pets][dogs][cats] contains a combination of ingredients that stops [blocks (interrupts)(terminates)] the flea life cycle and controls other listed insects. The first active ingredient is [Biolar®][brand name] the insect growth regulator which inhibits the development of the immature stages of the flea for 100 days [14 weeks][3 months] preventing them from reaching the adult stage. [Biolar®][brand name] is similar to insect growth hormones that occur naturally in insects. The second active ingredient is the botanical, Pyrethrum [an extract of a Chrysanthemum flower], which provides effective knock-down and quick-kill of insects upon direct contact.

The combination of ingredients in [Farnam Pet Spray 549][brand name] for [pets] [dogs] [cats] kills adult fleas and the hatching fleas [pre-adult (larval) fleas][eggs (hatching eggs)(larvae)] for 100 days [14 weeks][3 months] before they grow up to bite. [Biolar®][brand name][the insect growth regulator] continues to kill [control] hatching fleas [pre-adult (larval) fleas][eggs (hatching eggs)(larvae)] for 100 days [14 weeks][3 months] by preventing their development onto the adult biting stage. [Farnam Pet Spray 549][brand name] can also be used to control (kill)(interrupt)(terminate)(block)] fleas hidden in carpets, rugs, draperies, upholstery, pet bedding, floor cracks and cabinets. Occasionally adult fleas may be present in treated areas when reintroduced from infested animals.

As a part of a complete flea control program treat pet, treat indoor and outdoor areas where animals frequent by using EPA registered [brand name] outdoor [lawn][home and garden] spray, [brand name] [pressurized] [Ready-To-Use] [RTU] flea and tick [indoor] [premise] spray.

[Farnam Pet Spray 549] [brand name] may be applied as a direct, contact spray to control fleas, ticks and other listed insect pests on premises.

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[] OR () indicates alternate or optional wording

DIRECTIONS FOR USE

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

FOR DOGS [CATS] [PETS]: Cover animal's eyes with a hand. Do not spray directly on mouth, nose and eyes. Spray head, ears and chest until damp. With fingertips, rub into face, around mouth, nose and eyes. Then spray from the neck to the tail, finishing legs last. For best penetration of spray to skin and on heavily coated animals, direct spray against the natural lay of the hair, spraying the ruffled hair directly behind the hand. Make sure the spray thoroughly wets ticks. [When using on miniature and toy breeds of dogs or on cats, towel dry the animal after ½ hour if not totally dry.] Repeat treatment every 3 months. Avoid contact with genitalia.

FOR PUPPIES OVER 6 MONTHS AND KITTENS OVER 7 MONTHS: Wrap the animal in towel which has been sprayed lightly with this product. Leave eyes, nose and mouth exposed. Put some spray on the finger and gently rub around eyes, nose and mouth area. Keep the animal wrapped for 5 to 10 minutes. Fleas may then be removed from the coat by picking or combing. For best results, all dogs and cats should be treated with a similar flea control product such as [brand name] to prevent reinfestation of puppies and kittens. Do not spray directly on puppies and kittens. Repeat treatment every 3 months. Avoid contact with genitalia.

FOR USE IN PET [DOG] [CAT] AREAS AND OTHER AREAS WHERE [DOGS] [CATS] PETS FREQUENT: Treat pet [dog] [cat] bedding and other pet [dog] [cat] resting areas as these are primary hiding areas for fleas and ticks. To reduce infestation, spray around sleeping area, around baseboards, window and door frames, wall cracks, local areas of floors and other resting places until the surface is slightly moist. Also spray the entire inside surface of dog houses, [animal holding areas]. For best results, treat pet bedding, animal quarters, and other resting area [other listed pet areas]. No need to remove pet bedding after treatment. Do not allow pets to use treated areas until completely dry. Repeat as needed.

TO CONTROL OTHER LISTED PESTS: Apply as a direct spray to control accessible stages of listed insects. Spray to thoroughly wet exposed insects. Direct spray into hiding places, cracks and crevices, along baseboards and around door and window frames. Repeat as needed.

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
WARNING

HUMANS: Causes eye irritation. Do not get in eyes or on clothing. Harmful if swallowed or inhaled. Avoid breathing mist. Keep out of eyes. Avoid contamination of food. Wash hands with soap and water after use.

ANIMALS: Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing or medicated animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Keep out of lakes, streams, ponds, tidal marshes and estuaries. Do not apply where runoff is likely to occur.

PHYSICAL OR CHEMICAL HAZARDS: Flammable. Keep away from heat and open flame.

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FIRST AID	
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 the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
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 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 treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
In case of medical emergencies or health and safety inquiries, or in case of fire, leaking or damaged containers or for product use information, Call 602-285-1660	
Have product container or label with you when calling a poison control center or doctor, or going for treatment.	

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STORAGE AND DISPOSAL

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

Storage: Do not use or store near heat or open flame. Store away from children.

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.

Manufactured for:

FARNAM PET PRODUCTS – (800) 825-2555

A Division of Farnam Companies, Inc.

Phoenix, AZ 85013