6 JUN 1995

John B. Baker PFIZER Inc. DBA PFIZER Animal Health 1600 Paoli Pike West Chester, PA 19380

Subject: Formula Change For:
Esbiothrin Flea And Tick Mist
EPA Registration No. 37425-32
Application dated February 14, 1995

Dear Mr. Baker:

The proposed amendment to the registration of the product cited above under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended changing the formulation is acceptable. The Confidential Statement Of Formula submitted with your application is acceptable and has been made a part of the record for this product.

The draft labeling submitted with your application is acceptable subject to the comments listed below. A stamped copy is enclosed for your records.

1) Change the precautionary labeling to read as follows:

"Causes substantial but temporary eye irritation. Do not get in eyes or on clothing. Wear safety glasses. Harmful if swallowed or absorbed through skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

2) Under "If Swallowed", the "Note to Physician" is no longer necessary.

Submit two copies of the corrected finished printed labeling before the product is released for shipment under this revised labeling.

A copy of the review of the eye irritation study is enclosed for your records.

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

Sincerely,

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Richard P. Keigwin, Jr. Product Manager 10 Insecticide & Rodenticide Branch Registration Division (7505C)

PRECAUTIONARY STATEMENTS

Hazards to Humans and **Domestic Animals**

WARNING

HUMAN: Causes eye irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. ANIMAL: Avoid treatment of pets under 6 weeks of age. If treatment is necessary, use special instructions. Do not oversaturate, especially on cats. Avoid spraying of genital areas. **ENVIRONMENTAL** HAZARDS: This product is toxic to fish. Do not add directly to water. Do not apply where runoff is likely to occur. PHYSICAL OR **CHEMICAL HAZARDS:** FLAMMABLE. Keep away from heat and open flame. Contains alcohol. Do not apply to painted or finished wood surfaces.

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

> Use Only in a Well-Ventilated Area

DOGS AND CATS

Remove safety cap and insert sprayer. Cover animal's eves with hand and with a firm, fast stroke to get a proper spray mist, spray head, ears and chest until damp. With fingertips. rub into face around mouth, nose and eves. Then spray neck, middle and hindguarters, finishing legs last. For best penetration of spray to skin, direct spray against the natural lay of the hair. On long haired dogs, rub your hand against the lay of the hair, spraying the ruffled hair directly behind the hand. Make sure spray thoroughly wets ticks.

Repeat treatment asACCEPTED needed.

In EPA Letter Dated

with COMMENTSSmithKline Beecham Animal Health

West Chester, PA 19380

6 JUN 1995

Under the Enteral Insecticide, Fungicide, sur a standicide Act as amended, to, the pesticide registered under EPA Reg. No.

ESBIOTHRIN FLEA AND TICK MIST

INSECTICIDE, REPELLENT & DEODORANT FOR DOGS-PUPPIES-CATS-KITTENS

> **KILLS FLEAS-TICKS-LICE**

TEMPORARILY REPELS GNATS-FLIES-MOSQUITOES

ACTIVE INGREDIENTS: 0.30% **Esbiothrin** N-Octyl bicycloheptene dicarboximide 0.50% Di-n-propyl isocinchomeronate 0.50% Inert ingredients 98.70% TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

See Side Panel for Precautionary Statements

> EPA Est. No. 37425-FL-1 EPA Reg. No. 37425-32

Net Contents 32 fl.oz./946 mL

Directions for Use (continued) **NURSING PUPPIES ANI KITTENS** Spray only along back o

on your fingertips and ru into coat.

> PET'S SLEEPING QUARTERS

Spray around baseboard windows, door frames, wall cracks and local are of floor. If mosquitoes, gnats or flies are presen spray lightly into the air. Repeat as needed. The pet's bedding should be sprayed, making sure th area beneath the beddin is also sprayed. After spray has dried, remove old bedding and replace with fresh bedding. Tre pets with one of our registered flea and tick control products before allowing them to enter

HORSES

treated area.

To control stable flies, horse flies, deer flies and face flies, apply to face, legs, flanks, top line and other body areas commonly attacked by these flies. Repeat treatment as needed. Caution: do not use on horses intended for food

STATEMENT OF PRACTICAL TREATMEN IF IN EYES: Flush with plenty of water for 15