keg # 270-22.5

PM-14

AUG 2 2 1995

5488213

Farnam Companies Inc. 301 West Osborn Phoenix, AZ 85013-3928

Attention: Mr. Leland Veith

Subject: Fly-Off Lotion Insect Repellent for Dogs EPA Registration No. 270-225 Your amended application of August 6, 1992

The Agency has determined that the above application, which was submitted as a notification under PR Notice 88-6, was not eligible for such processing. You had based your claim for notification on the incorrect assertion that "Other Cube Resins" were now considered "inert". In contrast, the Rotenone Standard had specifically declared them to be "active". For this reason, we are now treating this submission as an amendment and have provided our comments on your revised Confidential Statements of Formula (CSF) and label.

A. Comments on CSF

The Confidential Statements of Formula (CSF), dated August 25 and 26, 1992, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are not acceptable for the reasons given below.

- 1. The CSF's are not signed (Block 18).
- 2. Blocks 5 (PM Team 14), 16, 17, 19, and 20 are not completed.
- 3. List "Other Associated Resins" as "repellent" in Block 15.

Resubmit your CSF with the above changes.

B. Comments on Label

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you make the following labeling changes:

1. As indicated on Page 24 of the Rotenone Standard, the ingredient statement for products must list the actives as:

Therefore, for this product, you must list "Other Associated Resins" as "0.168%".

- 2. Put a double asterisk (**) after "INERT INGREDIENTS". Immediately below, put "**Contains petroleum distillates".
- 3. Modify your "WARNING" section as follows:

WARNING

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

- 4. Change "Statement of Practical Treatment" to "FIRST AID".
- 5. Change "IF ON SKIN" to

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

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6. Revised your "Environmental Hazards" statements as follows:

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters. 7. Revise your use directions as follows:

DIRECTIONS FOR USE

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

Use Restrictions:

To protect dogs from flies, gnats, and mosquitos. Do not apply to puppies less than 4 weeks old. Do not apply to cats.

Application Directions:

Spray lightly ... dog's coat. Do not get in eyes, nose, or mouth.

3. In your DISPOSAL section, add the following sentence after "Do not reuse empty container".

Rinse bottle.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

Robert A. Forrest Product Manager (14) Insecticide-Rodenticide Branch Registration Division (H7504C)

Enclosures: 1. Stamped label 2. A-79 Enclosure

Peacock WP#6:A:ROTENONE:\270.225:305-5407,-6600:8/22/95

FRONT PANEL

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ACCEPTED with COMMENTS in EPA Letter Bated

AUG 2 2 1995

FLYS-OFF LOTION

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registered w	275

INSECT REPELLENT FOR DOGS

Protects Dogs From

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FLIES * GNATS * MOSQUITOS

*Equivalent to 0.3% (butylcarbityl)(6-propylpiperonyl) ether and 0.075% related compounds.

Keep Out Of Reach Of Children

WARNING

See back panel for additional cautions

Net Contents: 6 FL OZ

BACK PANEL

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

Keep out of reach of children. For external use only. Keep out of pet's eyes. Avoid contact with skin and clothing.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Do Not induce vomiting. Contact a physician immediately. Product contains aromatic solvents.

IF IN EYES: Flush with water for 15 minutes, contact a physician.

IF ON SKIN: Wash with soap and water.

IF INHALED: Remove victim to fresh air. Contact a physician if irritation persists.

ENVIRONMENTAL HAZARDS

Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.

PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

DIRECTIONS FOR USE

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

Spray lightly, or moisten cloth or sponge with Flys-O:f Lotion and rub on lightly. Use in and around ears, base of tail, and

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BACK PANEL

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underside. Also apply a thin film to dog's coat. Repeat treatment when necessary.

STORAGE AND DISPOSAL

STORAGE: Store tightly closed in a cool, dry place inaccessible to children and pets, and away from heat and sunlight. DISPOSAL: Do not reuse empty container. Wrap and put in trash.

EPA REG. NO. 270-225 EPA EST. NO. 34346-NB-1

> Manufactured For: Farnam Companies, Inc. Phoenix, Arizona 85013

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