JUN 1 1 1991

Mr. Alan Ebersold Boehringer Ingelheim Animal Health, Inc. Anchor Division 2621 North Belt Highway St. Joseph, MO 64502

Dear Mr. Ebersold:

Amendment - Addition of Deer Tick Claim Subject:

Permectrin II

EPA Registration No. 4691-108

Permectrin Pet, Yard and Kennel Spray

EPA Registration No. 4691-109

Your Applications Dated November 19, 1990

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes indicated below prior to release for shipment of product bearing the amended labeling.

- For both of the subject product, make the following 1. labeling changes:
 - Add the following precaution under the Direction For Use:

Do not use on sick, old or debilitated animals.

Delete the statements of practical treatment under b. the Precautionary Statement section and identify them under the heading and format:

STATEMENT OF PRACTICAL TREATMENT

- IF SWALLOWED Call a physician or Poison Control Center immediately. INDUCE DO cause VOMITING. Vomiting may aspiration pneumonia.
- IF ON SKIN -Remove conta inated clothing and was affected ares with soap and water.
- IF IN EYES -Flush eyes with plenty of water Call a physician immediately.

LEA WHA

If INHALED - Remove victim to fresh alr. Apply artificial respiration if indicated.

- c. Add footnote to the ingredient statement indicating: *Contains petroleum distillates.
- 2. For EPA Reg. No. 4691-108, make the following changes:
 - a. Delete "long-lasting" from the labeling since you have not supplied/cited data justifying this claim as requested in our August 3, 1988 letter.
 - b. Delete "... and small animals" or identify. We assume you are referring to dogs. If so then state Pests on Swine, sheep, poultry and dogs." If dogs are retained on the label then comment 3a below (puppies only) also applies.
 - c. Since the product if for agricultural use add the following statement to the front panel:

"For Agricultural Use Only"

- 3. For EPA Reg. No. 4691-109, make the following changes:
 - a. Add the following precautions under Directions For Use:

Do not use this product on puppies or kittens less than 3 months old.

- b. Revise the format of the Storage and Disposal section as it appears in EPA Reg. No. 4691-108.
- c. Refer to comment 2b above. the same comment applies here.
- d. The product is approve for use on dogs and cats. Thus either delete "pet" and replace with "dog and cat" or qualify the term pet with dog and cat throughout the label.
- e. Under directions you state to treat not more than once every two weeks, however under the application column you say to treat 7 to 14 days later. Please clarify.

Submit five copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

We have no record of a response to our August 3, 1988 letter regarding potential toxicity to cats from a dip application. A copy of this letter is enclosed. Please respond.

Sincerely,

George T. LaRocca Product Manager 13 Insecticide-Rodenticide Branch Registration Division (H7505C)

Enclosure

BEST AVAILABLE COPY

Pennectrin*

Pet, Yard and Kennel



Long Lasting Pet and Premise Spray

Controls and Kills Deer Ticks (Carrier of Lyme Disease)

10% Emulsifiable Insecticide KEEP OUT OF REACH OF CHILDREN

CAUTION See back panel for additional precoutionary tratements.

Permethrin (3-phenoxyphenyl) methyl (1)-cis, trans-3(2,2 dichloroethenyl)-2,2dimethyleychipeopanecarboxylate* 10 00% facet Ingredients 20 00%

100,00% *Ch/trans ratio: Alin. 35% (r) cia, and mau. 85% (r)trans immers. -Cantolna 8.73 his permethele per geline.

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COSE OF Synt on Boar or poved surfaces, south up with sand, earth
alsochert. Remove to chemical waste area and disposa of in alsomboth Remove to Chemical waste area and dispose of in-most state and local regulations. Do red seuse container. For equivalent there after for recycling is reconstituting or proclass of in a santary breakly, or beforeration, in, if admined by sta-authorities, by business it business, stay out of smoke Wrister resulting from the use of this greater may be disposed as an approved waste disposal tackey.

EPA Reg No 4691-109 EPA ESI No 6175 iw Ancher Birlisten, Banbringer janethelm Anlmal St. Arreph, Mesmet 64502 U.S.A.

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Read Directions Before Using

Product Use	Dilution for Use	Application
Fleas, lice, mange mites, ticks, including Deer Ticks (carrier of tyme disease). Pests on small animals (dogs and cats). Spraying kennels, dog houses, runs and yards.	Hix 8 or in 25 gal or 1 or in 3 gal of clean water for area or spot applications. Hix 8 or in 6.3 gal or 14 or in 3 gal of clean water.	Sponge on cats. Dip, spray, or sponge on dogs. Apply solution until skin is wet. Allow to dry. As a guide, use 1 pint per medium-sized dog. For lice or mites, a second treatment is recommended 7 to 14 days later. Spray all surfaces to point of run-off with diluted spray. As a guide, use 1 gallon per 750 sq.

DIRECTIONS FOR USE IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PROPUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

ror use on pets and their premises for control of flies, fleas, lice, mites and ticks, including. Deer Ficks (carrier of Lyme Disease). Mix PERMECTRIN 11 Pet, Yard & Konnel Spray and apply the diluted material to animals and pest breeding or resting surfaces at the rates shown. In the accompanying chart. These dilutions and rates will provide most efficient pest control under conditions of heavy pressure when good contact is achieved. Accompanying manure removal and sanitation practices should precede sprays. Do not spray feed, food or water. Setreat as needed but not more than once every two weeks.

Anchor Division Boehringer Ingelheim Animal Health, Inc.

PRICAUIMPANT STATIME :

CARTIBLE May be harmful II swallowed, belated or absorbed through the formed breathing spray nest Avoid contact with this, eyes, or closing to case of the contact, which show the property of water in case of the contact, wash this with soap and water. Cet medical attention It breather possible II swallowed, call a physician. Vaniling though to exprevised by a physician because of possible primorary demand the to application of the solvent De not allow children to hardle or apply this product.

ENGINEMMENTAL MASAGES

This posticible is entremely feetic to high Use with care when applying to away adjacent to any body of water. Do not apply directly to water the not contaminate water by closwing of equipment or disposal of wastes. Apply this product only as specified on this label.

PHYSICAL OR CHILDICAL MAZAROS.

Do not use or store near heat or open flame

STORAGE AND DISPOSAL

Do not contantonate water, load or teed by steage or disposal SEEP CONTAINER SEALON WHEN HOT IN USE, PROTECT JOBER PRETRING to case of spill on floor or paved surface; snak up with savel easily or synthetic absorberd. Remove to chamical was area and dispose of the accurdance with state and local regulations. Do not reuse container this base (or equivalent). Then offer for recycling or recombinating or procture and dispose of the a sanitary lamidit, or incinceration, or, it allowed by state and local authorities, by burning it becomed, stay out of smake.

Master resulting from the use of tide product way be disposed of on size or

Wastes resulting them the use of their product may be disposed of on site or of an approved waste disposal facility.

EPA Reg. No. 4631-109 EPA Est. No. 6175 LA-1
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St. Joseph, Missout 44502 U.S.A.
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