

NOV 27 1996

DVM Pharmaceuticals, Inc.  
c/o RegWest Company  
Greeley, CO 80632-2220

Attention: Ms. Kim Davis

Subject: Durakyl Pet Dip  
EPA Registration No. 41835-6  
Your amended application of April 9, 1996  
Our letter of May 2, 1996  
Recent Report of Incidents Involving Cats

In your amended application of April 9, 1996, you had submitted revised labeling and a revised Confidential Statement of Formula (CSF). In our response of May 2, 1996, we had requested revised labeling and your reaction to our proposed existing stocks provisions. In our letter we also noted that you were still marketing this product, but, since February 1995, not for "cats", a use that had resulted in five deaths earlier this year and in two earlier deaths in the previous 10 years.

Because of the following developments, we have decided to respond to the above amendment before receiving the requested revised labeling and response to our proposed existing stocks provisions:

1. We failed to comment on the acceptability of your revised CSF of April 9, 1996.
2. On July 24, 1996, the Agency cancelled your previous sources for this product for failure to pay maintenance fees.
3. Agevo is not supporting the pet use of Rotenone for re-registration.

A. Revised CSF Dated April 9, 1996

The Confidential Statement of Formula (CSF), dated April 9, 1996, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is not acceptable for the reasons given below.

1. Agevo has requested that pet uses be eliminated from the label of your proposed source product.

As long as you have legal supplies of your old source, you may continue to market this product, with the labeling restrictions listed below. After those supplies are exhausted and if you do not receive approval for another legal source, you may no longer market this product.

#### B. Revised Labeling of April 9, 1996

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 changes and submit one (1) copy to us before you ship your product:

1. Based on the earlier studies for EPA Reg. No. 432-684, which is similar to your last source product, EPA Reg. No. 432-664, you will need to revise your precautionary statements as follows:

#### PRECAUTIONARY STATEMENTS

##### Hazards to Humans and Domestic Animals

WARNING: May be fatal if swallowed Causes substantial but temporary eye injury. Wear safety glasses. Causes skin irritation. Harmful if absorbed through the skin. Do not get in eyes, on skin or on clothing. Avoid breathing vapors or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

#### FIRST AID

If Swallowed: ... be a hazard.

If On Skin: Wash with plenty of soap and water. Get medical attention.

If In Eyes: Flush with plenty of water. Call a physician.

##### Environmental Hazards

This product ... washwaters.

##### Physical or Chemical Hazards

Do not ... 120 Deg. F.

2. Under the ingredient statement, add "Contains Petroleum Distillates".

C. Existing Stocks Provisions of Previously Approved Labeling

Now that the Agency has approved the revised labeling, with comments, submitted with your amendment application of April 9, 1996, you will have 18 months (or until June 1, 1998) to use labeling that was previously approved, provided that the cat use does not appear on the label of the product. This should not be a problem since as noted above, DVM Pharmaceuticals, Inc. has not marketed the product with this use since February 1995.

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.

If you have questions about this letter, please contact Mr. Dan Peacock at 703-305-5407.

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

Sincerely yours,

William W. Jacobs, PhD  
Product Manager (14)  
Insecticide-Rodenticide Branch  
Registration Division (H7504C)

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

cc: 1. Ms. Deanna Pfann  
      9901 Pinelake Drive  
      Houston, TX 77055

2. Mr. James Redd  
   EPA Region 6  
   1445 Ross Ave.  
   12th Floor Suite 1200  
   Dallas, TX 75202-2733

Peacock WP#10:A:\Rotenone\41835-6.NOV:305-5407,-6600:11/25/96

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# DuraKyl

## Pet Dip

To Kill Fleas, Ticks and Lice  
on Dogs  
(4 Weeks or Older)

### ACTIVE INGREDIENTS:

Rotenone .....	1.1%
Other Associated Resins .....	2.2%
Pyrethrins .....	0.8%
<b>INERT INGREDIENTS .....</b>	<b>95.9%</b>
	100.0%

**PRECAUCION AL CONSUMIDOR:** Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

**TRANSLATION:** To the user, if you cannot read English, do not use this product until the label has been fully explained to you.

**ACCEPTED  
with COMMENTS  
by EPA Letter Dated**

**NOV 27 1996**

*Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended for the pesticides  
registered under EPA Reg. No.  
41835-6*

Keep Out of Reach of Children  
**WARNING**  
See back panel for additional  
precautionary statements.

Net Contents:      Fl. Oz. (     Tbs.)

DVM Pharmaceuticals, Inc. (Dist.)  
Miami/Florida/33172

**[Back Panel]**

### PRECAUTIONARY STATEMENTS Hazards to Humans & Domestic Animals

**WARNING:** May be fatal if swallowed. Causes substantial but temporary eye injury. Harmful if absorbed through the skin. Causes skin irritation. Wear safety glasses. Do not get in eyes, on skin or on clothing. Avoid breathing vapors or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

#### Statement of Practical Treatment

**If Swallowed:** Call a physician or poison control center. Do not give milk, cream or oily substances containing vegetable or animal fats. Drink large quantities of water. Avoid alcohol. Do not induce vomiting or give anything to an unconscious person. This product contains aromatic petroleum solvents. Aspiration may be a hazard. **If On Skin:** Wash with plenty of soap and water. Get medical attention if irritation persists. **If In Eyes:** Flush with plenty of water. If irritation persists, get medical attention.

#### Environmental Hazards

This product is extremely toxic to fish. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters.

#### Physical and Chemical Hazards

Do not use or store near heat or open flame. Flash point minimum 120°F.

### DIRECTIONS FOR USE

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

**USE RESTRICTIONS:** For use on dogs four (4) weeks or older, to control fleas, ticks and lice.

**MIXING DIRECTIONS:** Depending upon the species and age of pet and the species of pest, dilute this product, using the enclosed measuring device.

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**FLEAS AND LICE:**

**ADULT DOGS:** Dilute DuraKyl Pet Dip at the rate of 1 oz. (2 TBS) per 1 gallon of water.

**PUPPIES 4 WEEKS OR OLDER:** Dilute DuraKyl Pet Dip at the rate of ½ oz. (1 TBS) per 1 gallon of water.

**TICKS:**

**ADULT DOGS:** Dilute DuraKyl Pet Dip at the rate of 2 oz. (4 TBS) per 1 gallon of water.

**PUPPIES 4 WEEKS OR OLDER:** Dilute DuraKyl Pet Dip at the rate of 1 oz. (2 TBS) per 1 gallon of water.

Note: Rarely, some animals, especially older animals, may be more sensitive to this product. If an animal shows symptoms of distress (such as tremors, stiffness or dilated eyes), immediately discontinue treatment, rinse the animal thoroughly with water, and take it and this bottle to a veterinarian or animal hospital.

**APPLICATION DIRECTIONS:** Apply directly to animal as a spray, sponge-on or a wash until skin is wet. Avoid contact with eyes, nose or mouth or wounds. Do not rinse. Allow to air dry. Repeat treatment as needed.

**STORAGE AND DISPOSAL**

**STORAGE:** Store only in original container in a dry place inaccessible to children and pets. **DISPOSAL:** Do not reuse empty container. Rinse thoroughly. Securely wrap and discard in trash.

EPA Reg. No. 41835-6  
EPA Est. 62478-FL-01

Product No. 6-5660  
Rev. 0496