

United States Environmental Protection Agency

Ms. Kim Davis, CC, APC Consultant/Agent
DVM Pharmaceuticals, Inc.
c/o RegWest Company
38056 Rocky Road
Greeley, CO 80631-9375

DEC 12 2002

Subject: Submission of revised labeling per PR Notice 96-6, 97-4, 97-5, 97-6, 2001-1, and 2001-6.

Product Name: DVM Shampoo Concentrate
Registration Number: 41835-12
Date of Submission: October 25, 2002
OPP Identifier No. 281912

Dear Ms. Davis,

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable subject to the comments listed below. Five copies of the finished labeling must be submitted prior to releasing the product for shipment.

1. Page 1 within the product attribute claims, remove the word "Natural" from the statement "Contains Natural Pyrethrins." This statement is false and misleading under 40 CFR 156.10.
2. Page 1 remove the statement "To be Applied only By or Under the Supervision of a Licensed Veterinarian or Animal Groomer." This statement is unenforceable under FIFRA, and the product is not a restricted use pesticide product. This statement is therefore, false and misleading under 40 CFR 156.10.

If you have any questions, you may contact Richard J. Gebken, at (703) 305-6701.

Sincerely,

Richard J. Gebken

for

Joseph Tavano
Acting Product Manager 10
Insecticide Branch
Registration Division (7505C)

Enclosure

041835-00012 S625029.wpd

CONCURRENCES

SYMBOL ▶	H7505C							
SURNAME ▶	RGEBKEN							
DATE ▶	Dec 12, 2002							

DVM Shampoo Concentrate

[To be Applied Only By or Under the Supervision of a Licensed Veterinarian or Animal Groomer]

Contains Natural Pyrethrins

A Concentrate to be Added to Shampoos

For Use on Dogs and Cats to Kill Fleas and Ticks

Active Ingredients:

Pyrethrins (CAS No. 8003-34-7)	7.5%
*Piperonyl Butoxide, Technical (CAS No. 51-03-6)	75.0%
Other Ingredients**	17.5%
Total	100.0%

*Equivalent to min. 60% (butylcarbityl) (6-propylpiperonyl) ether and 15% related compounds.

**Contains petroleum distillates.

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

Net Contents: _____ fl. oz. (_____ ml)

EPA Reg. No. 41835-12 EPA Est. _____

A veterinary product distributed by
DVM Pharmaceuticals, Inc.
50 N.W. 176th Street
Miami, FL 33169
Telephone: (305) 575-6200

ACCEPTED
with COMMENTS
In EPA Letter Dated:
DEC 12 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
41835-12

{Back Panel}

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS OR CATS

DIRECTIONS FOR USE

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

To shampoo and kill fleas and ticks, follow these easy steps:

1. Mix 1 oz. of DVM Shampoo Concentrate in 1 gallon of non-insecticidal shampoo.
2. Thoroughly wet animal.
3. Apply a generous amount of shampoo mixture to the animal's coat, massaging the lather well into the coat and skin.
4. Allow the lather to remain on animal for five minutes to permit pyrethrins to take full effect.
5. Thoroughly rinse the animal.
6. Do not repeat treatment for one week.

Storage: Store in original container in a cool, dry (preferably locked) place inaccessible to children and pets.
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 undiluted product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: Humans: Harmful if swallowed. Do not get in eyes. Thoroughly wash hands after each use and before eating or smoking. **Animals:** Do not apply directly to or on eyes, mouth or genitalia of pets. Do not use on debilitated, aged, pregnant or nursing animals. Do not use on puppies or kittens under 12 weeks of age. Certain medications can interact with pesticides. Consult a veterinarian before using on 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, immediately consult a veterinarian.

First Aid

If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give any liquid to the person. • Do not give anything by mouth to an unconscious person.
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 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.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. [You may also contact 1-800-222-1222 {or other appropriate number} for emergency medical treatment information.]	
Note to Physician: Contains petroleum distillate – vomiting may cause aspiration pneumonia.	

{Note: The first aid statements' grid format will be used if market label space permits; otherwise, a paragraph format will be used.}

Environmental Hazards

This product is toxic to fish. Do not apply directly to any body of water. Do not contaminate water by cleaning of equipment or disposal of waste.

Warranty Statement: Our recommendations for use of this product are based upon tests believed to be reliable. The use of this product being beyond the control of the manufacturer, no guarantee, express or implied, is made as to the effects of such or the results to be obtained if not used in accordance with directions or established safe practice. The buyer must assume all responsibility, including injury or damage, resulting from its misuse as such, or in combination with other materials.

Product No. _____

REV _____

[] Denotes alternate/optional language

{ } Denotes language that does not appear on the market label