

13799-20

02/12/2007

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FEB 12 2007

FOUR PAWS Products LTD
50 Wireless Blvd.
Hauppauge, NY 11788

Dear Mr. Birk:

Subject: Label Revisions

EPA Registration Number: 13799-20

Product Name: FOUR PAWS EAR MITE REMEDY for DOGS & CATS

Application Date: October 18, 2006

The labeling referred to above, submitted in connection with registration under The Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed above.

- 1) The Precautionary Statements should be revised to read as follows:

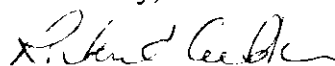
PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
CAUTION

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

- 2) The claim "Healing Remedies" is misleading and cannot be added to the label, this claim indicates a medical use.

Enclosed is a copy of your label stamped "Accepted with Comments". Submit three (3) copies of the revised labeling for review before you release this product for shipment. If you have any questions regarding this letter contact Ms Pat Quarles @ 703-305-6876.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division 7505

enclosure

FRONT LABEL
FOUR PAWS EAR MITE REMEDY
EPA REG. NO. 13799-20

**ACCEPTED
WITH COMMENTS
In EPA Letter Dated:**

FEB 12 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
amended, for the purpose
and under EPA F

13799-20

Four Paws®
Healing Remedies
Ear Mite Remedy
For Dogs & Cats

Contains the Grooming Ingredient Aloe Vera

Effective in Killing Ear Mites

Active Ingredients:

Pyrethrins.....	0.10%
*Piperonyl butoxide, technical.....	1.05%

Inert Ingredients:	98.85%
	100.00%

Contains Petroleum Distillate

*Equivalent to 0.84% (butylcarbityl) (6-Propyl piperonyl) ether and 0.21% related compounds.

**KEEP OUT OF REACH OF CHILDREN.
CAUTION**

Net . Wt. 3/4 oz. (22 cc)

BACK LABEL
FOUR PAWS EAR MITE REMEDY
EPA REG. NO. 13799-20

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**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS AND CATS**

Four Paws®
HEALING REMEDIES
EAR MITE REMEDY
For Dogs and Cats
Contains the Grooming Ingredient Aloe Vera

FOUR PAWS EAR MITE REMEDY KILLS EAR MITES AND CONTAINS THE GROOMING INGREDIENT ALOE VERA. IT ALSO AIDS IN WAX REMOVAL.

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

**FOR EXTERNAL USE ONLY
SHAKE WELL BEFORE USING**

To Kill Ear Mites and Aid in the Removal of Ear Wax: Apply 5 drops of solution in ear and gently massage base of ear for 3-5 minutes. Leave solution in ear for another few minutes and the allow dog or cat to shake its head to remove as much solution as possible. Wipe the remainder of the liquid from the ear with cotton. Repeat treatment every other day until condition is relieved. Improvement is usually noted after two applications. This solution applied twice monthly will reduce the possibility of ear mite infestation and the accumulation of ear wax. Do not use on puppies or kittens under 12 weeks of age. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals, or animals on medication. 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, consult a veterinarian immediately.

DIAGNOSIS

Ear mites normally cause a dry, dark, brown, waxy, exudate with crust in the ears of dogs. The mites are easily observed by placing some of the ear exudate on a dark surface and watching carefully for white specks walking away. DO NOT probe, swab or injure the delicate tissue of the ear when removing exudate. Inflamed, watery or blocked ear canals indicate a more serious condition which requires the services of a veterinarian.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: Harmful if swallowed. Avoid contact with skin and eyes. Do not contaminate food or feedstuffs with this solution. Do not use for prolonged periods of time. If condition persists or if irritation develops, discontinue use and consult a veterinarian.

Environmental Hazards: This product is toxic to fish, birds and other wildlife. Do not contaminate any body of water with this solution.

Physical Hazards: Do not store or use near heat or open flame.

FIRST AID

If on skin or clothing: 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.

If in eyes: 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 swallowed: Immediately call a poison control center or doctor. Do not induce vomiting unless told so to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person. Note to Physician: Contains petroleum distillate – vomiting may cause aspiration pneumonia.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of emergency or for product use information, call (631) 434-1100 9AM-5PM EST, Monday through Friday.

STORAGE AND DISPOSAL

Storage: Store in a cool, dry area away from heat or open flame.

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 product down any indoor or outdoor drain.

Four Paws® Products, Ltd.
Hauppauge, NY 11788-USA
Item No. 01730
EPA Reg. No. 13799-20
EPA Est. No. 43395-NY-1

UPC CODE

Made in U.S.A.