

OCT 25 1996

Mr. Terry McNamara
Bayer Corporation
Agriculture Division, Animal Health
P.O. Box 390
Shawnee Mission, KS 66201-0390

Dear Mr. McNamara:

Subject: Revised labeling
Advantage 20
EPA Registration No. 11556-119
Amendment application of August 27, 1996

The amendment referred to above, submitted in connection with registration under FIFRA, is acceptable provided that you:

Delete the statement "Quickly eliminates the cause of flea allergy dermatitis" implied drug claim and is unacceptable.

Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 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

DHE

Dennis H. Edwards, Jr.
Product Manager (19)
Insecticide Rodenticide Branch
Registration Division (7505C)

Enclosure

Reason to Issue:

Date: 10/18/96

Supersedes: 8/13/96

299

(Front Panel)

Advantage™ 20
Flea Adulticide

Once-A-Month Topical Flea Treatment
For 11-20 lb. Dogs

For the Prevention and Treatment of Flea Infestations on Dogs

ACCEPTED
with COMMENTS
in EPA Letter Dated

OCT 25 1996

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

11556-119

- Available Only Through Licensed Practicing Veterinarians
- Kills 98-100% of the Fleas on Dogs Within One Day of Treatment
- One Treatment Prevents Further Flea Infestation For At Least Four Weeks
- Kills Fleas Before They Lay Eggs

Active Ingredient	% By Weight
Imidacloprid; 1-[(6-Chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine ...	9.1%
Inert Ingredients	90.9%
Total	100%

KEEP OUT OF REACH OF CHILDREN

WARNING

See Below for Statements of Practical Treatment and Precautionary Statements

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS

Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling. Keep out of reach of children. Do not contaminate feed or food.

HAZARDS TO DOMESTIC ANIMALS

For external use only.

Do not use on puppies under four months of age.

As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals. If your animal is on medication, consult your veterinarian before using this or any product.

Reason to Issue:

389
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STATEMENTS OF PRACTICAL TREATMENT

If in eyes: Hold eyelids open and flush with plenty of water. Get medical attention if irritation persists.

If swallowed: Call a physician or Poison Control Center.

If on skin: Wash with plenty of soap and water.

To Physician: Treat the patient symptomatically.

Four 1.0 mL Tubes

EPA Est. 11556-DEU-1
EPA Reg. No. 11556-119

Manufactured For
Bayer Corporation
Agriculture Division
Animal Health
Shawnee Mission, Kansas 66201 USA

Reason to Issue:

Date: 10/18/96
Supersedes: 8/13/96

4 9 9

(Back Panel)

Advantage™ 20

Flea Adulticide

Fast

Effective

Once-A-Month Topical Flea Treatment for 11-20 lb. Dogs

- Available only through licensed practicing veterinarians
- Kills fleas within 24 hours
- Prevents reinfestation for at least 4 weeks
- Quickly eliminates the cause of flea allergy dermatitis
- Convenient, easy to apply

Four 1.0 mL Tubes

599

(Inside Left Panel)

Advantage™ 20

Flea Adulticide

Once-A-Month Topical Flea Treatment for 11-20 lb. Dogs

For the Prevention and Treatment of Flea Infestation on Dogs

DIRECTIONS FOR USE

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

HOW TO APPLY

1. Use only on dogs. Do not use on other animals.
2. Remove one applicator tube from the package.
3. Hold applicator tube in an upright position. Pull cap off tube.



4. Turn the cap around and place other end of cap back on tube.



5. Twist cap to break seal, then remove cap from tube.



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6. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to apply the entire contents directly on the skin.

Do not get this product in your pet's eyes or mouth.

Avoid contact with treated area until dry.



7. Discard empty tube as described in Storage and Disposal.

Advantage™ will kill 98-100% of the fleas on dogs within one day of treatment and will continue to protect the dog from further flea infestation for at least four (4) weeks. Reinfestation from the emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated.

Monthly treatments are required for optimal control and prevention of fleas.

Advantage remains efficacious following exposure to water or sunlight. Shampooing of the dog may shorten the duration of flea protection, therefore reapplication following shampooing is recommended. If re-treatment becomes necessary earlier than four weeks, do not re-treat more than once weekly.

Reason to Issue:

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799

(Inside Right Panel)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a cool, dry place. **Pesticide Disposal:** Securely wrap original container in several layers of newspaper and discard in trash. **Container Disposal:** Do not reuse empty container. Wrap container and put in trash.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer Corporation is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

EPA Est. 11556-DEU-1

EPA Reg. No. 11556-119

Reason to Issue:

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(Label on Individual Tube)

Advantage™

9.1% Imidacloprid

1.0 mL

EPA Reg. No. 11556-119

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

Reason to Issue:

Date: 10/18/96
Supersedes: 8/13/96

999

(Back of Blister Package)

