

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PRÉVENTION, PESTICIDES AND TOXIC SUBSTANCES

DEC 3 0 2008

Iain Weatherston Andrew M. Martin Co.,NV, Inc. 1802 N. Carson Street, Suite 212-2808 Carson City, NV 89701

SUBJECT: Application for Pesticide Notification (PRN 98-10)

Request General Label Change (Add U.S. Standard Units to Net Contents

Statement)

EPA Reg. No. 75844-8

Application Dated September 19, 2008

## Dear Registrant:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 09/19/08 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely,

Linda Arrington

Notifications & Minor Formulations Team Leader Registration Division (7505P)

Office of Pesticide Programs

<u>Please read instructions on reverse before completing form.</u> Form Approved. OMB No. 2070-0060. Approval expires **OPP Identifier Number** Registration **United States Environmental Protection Agency** Amendment Washington, DC 20460 Other Application for Pesticide - Section I 1. Company/Product Number 2. EPA Product Manager 3. Proposed Classification 75844-8 George LaRocca None Restricted 4. Company/Product (Name) PM# FREEDOM 50 PLUS IGR SPOT ON FOR DOGS 13 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical Debits (car) labeling Andrew M. Martin Co., NV. Inc. 1802 N. Carson Street, Suite 212-2808 EPA Reg. No. carson City, NV 89701 Check if this is a new address **Product Name** Section - II Amendment - Explain below. Final printed labels in repsonse to Agency letter dated "Me Too" Application. Resubmission in response to Agency letter dated \_ Notification - Explain below. Other - Explain below. Explanation: Use additional page(s) if necessary. (For section I and Section II.) To add U.S. Standard units (fl oz) to the net contents statement which currently only has metric units (cc). This notification is consistent with the provisions of PRN 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 19 U.S.C. Sec. 1001 to wilfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PRN 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA Section - III 1. Material This Product Will Be Packaged In: Child-Resistant Packaging Unit Packaging Water Soluble Packaging 2. Type of Container Matal Yes Yes Yes **Plastic** No No No Glass Paper If "Yes" If "Yes" No. pér No. per \* Certification must Unit Packaging wgt. Other (Specify) container Package wgt container be submitted see attached sheet 1,2,3, 4, &12 3. Location of Net Contents Information 5. Location of Label Directions 4. Size(s) Retail Container see attached sheet Label Container 6. Manner in Which Label is Affixed to Product Other Lithograph Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Title Telephone No. (Include Area Code) Name Iain Weatherston 623-353-4060 Senior Regulatory Consultant 6. Date Application Certification Received I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or (Stamped)

3. Title

5. Date

Senior Regulatory Consul;tant

Sept. 19, 2008

Weathers or

both under applicable law.

2. Signature

4. Typed Name

lain Weatherston

# ATTACHMENT TO PESTICIDE APPLICATION FORM 8570-1

Section III, box 4,

0.046 fl oz, 1.35 cc applicators will be sold in packs of 1, 3 and 12

0.092 fl oz, 2.70 cc applicators will be sold in packs of 1 and 3

0.183 fl oz, 5.40 cc applicators will be sold in packs of 1 and 3

8.12 fl oz, 240 cc bottles will be sold in packs of 1, 4 and 6

16.23 fl oz, 480 cc bottles will be sold in packs of 1 and 4.

Front panel

# FREEDOM 50 PLUS IGR SPOT ON FOR DOGS

(Cat/slash icon)

For use on dogs and puppies over twelve weeks of age

#### DO NOT USE ON CATS

[Kills, repels and prevents re-infestation of fleas for up to 5 weeks] [Kills, repels and prevents re-infestation for fleas for up to 4 weeks]

[Kills flea eggs and larvae for up to 8 weeks]

[Kills flea eggs and larvae for up to 6 weeks]

[Kills flea eggs and larvae for up to 4 weeks]

[Breaks the flea life cycle]

[Kills, repels and prevents re-infestation of ticks for up to 6 weeks]
[Kills, repels and prevents re-infestation of ticks for up to 4 weeks]
[Kills or repels mosquitoes, lice and mites on dogs for up to 4 weeks]

**ACTIVE INGREDIENT** 

# KEEP OUT OF REACH OF CHILDREN

# **CAUTION**

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

NOTIFICATION

DEC 3 0 2000

Andrew M. Martin Co., NV Inc. 1802 Carson Street, Suite 212-2808 Carson City, NV 89701

EPA Registration No. 75844-8 EPA Establishment No. 75844-CA-02 Package contains a two [2], three [3], six [6], twelve [12] months supply. (as applicable)

#### **Net Contents**

3 x 0.046 fl oz applicators; 3 x 0.092 fl oz applicators; 2 x 0.183 fl oz; 12 x 0.046 fl oz 8.12 fl oz bottle with dosing gun; 16.23 fl oz bottle with dosing gun.

3 x 1.35 cc applicators; 3 x 2.70 cc applicators; 2 x 5.4 cc applicators; 12 x 1.35 cc applicators 240 cc bottle with dosing gun; 480 cc bottle with dosing gun.

[ ] alternative or optional verbiage

<sup>\*</sup> Cis/trans ration: max 55% [±] cis and min 45% [±] trans

#### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Hazards to Humans: Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before re-use. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Hazards to Domestic Animals: For external use on dogs only. Do not use on cats or animals other than dogs. Consult a veterinarian before using this product on debilitated, aged or medicated animals, pregnant or nursing pups. Consult a veterinarian before using on dogs with known organ dysfunction. Sensitivities can occur after ANY pesticide product for animals. If signs of sensitivity occur, discontinue use, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Signs of sensitivity include skin sensitivity, increased itchiness, redness, rash, hair discoloration or hair loss at the application site and lethargy.

#### DO NOT USE ON CATS.

Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or unconditional muscle movements. If this occurs, immediate veterinary care should be provided

#### **FIRST AID**

#### IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
  - Do not induce vomiting unless told to by a poison control center or doctor.

#### 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 after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Rocky Mountain Poison Control at 1-303-595-4869 for medical treatment advice.

#### **ENVIRONMENTAL HAZARDS**

This product is extremely toxic to fish and other aquatic organisms. Do not allow treated dogs to go swimming for 12 hours following treatment.

#### **CHEMICAL HAZARDS**

Do not use or store near heat or open flame.

#### STORAGE AND DISPOSAL STATEMENTS

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

PESTICIDE STORAGE:

Store on a cool, dry place. Protect from freezing.

PESTICIDE DISPOSAL:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place

in trash. Never pour unused product down the drain or on the ground.

CONTAINER DISPOSAL (tubes): If empty: Do not reuse or refill this container. Place in trash or offer for

recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions.

Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL (bottle): Nonrefillable container. Do not reuse or refill this container. Place in

trash or offer for recycling

If partly filled: Call your local solid waste agency for disposal instructions.

Never place unused product down any indoor or outdoor drain.

#### **DIRECTIONS FOR USE**

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

#### DO NOT USE ON CATS

Ready to use, no dilution necessary.

- Hold tube in upright position pointing away from user's face and body. Break off tip or cut with scissors. Apply FREEDOM 50 Plus IGR Spot On For Dogs as follows by gently squeezing the applicator.
- Part dog's hair between shoulder blades.
- Apply recommended amount of solution to the skin on the dog's back between the shoulder blades. For large and extra-large dogs, application of the solution to the skin directly in front of the base of the dog's tail is also required. SEE RECOMMENDED DOSING GUIDELINES BELOW.

Package for dogs weighing 33 lbs or less

Apply 1.35cc of FREEDOM 50 Plus IGR Spot On For Dogs to the skin of the dog's back between the shoulder blades.

Package for dogs weighing 33 - 66 lbs

Apply 1.35cc of FREEDOM 50 Plus IGR Spot On For Dogs to the skin of the dog's back between the shoulder blades and 1.35cc to the skin directly in front of the base of the dog's tail.

Package for dogs weighing more than 66 lbs

Apply 2.70 cc of FREEDOM 50 Plus IGR Spot On For Dogs to the skin of the dog's back between the shoulder blades and 2.70 cc to the skin directly in front of the base of the dog's tail.

Multi package

For dogs weighing 33 lbs or less

Apply 1.35 cc of FREEDOM 50 Plus IGR Spot On For Dogs (1 tube) to the skin of the dog's back between the shoulder blades.

For dogs weighing 33 - 66 lbs

Apply 1.35 cc of FREEDOM 50 Plus IGR Spot On For Dogs (1 tube) to the skin of the dog's back between the shoulder blades and 1.355 cc (a second tube) to the skin directly in front of the base of the dog's tail.

For dogs weighing more than 66 lbs

Apply 2.70 cc of FREEDOM 50 Plus IGR Spot On For Dogs (2 tubes) to the skin of the dog's back between the shoulder blades and 2.70 cc (another 2 tubes) to the skin directly in front of the base of the dog's tail.

Dosing Gun (For use only with the 240 and 480 cc bottles in kennels, shelters and boarding and grooming establishments)

Use the FREEDOM PRE-FIXED 1.35 cc dosing gun in the same manner as the individual tubes. To mount the bottle on to the gun hold the gun upside down, slide bottle collar onto the bottle, insert puncture barb into bottle and then tighten the collar to the gun. Dose animals as described above for individual tubes.

#### WARRANTY

Andrew M. Martin Co., NV Inc., warrants that this product conforms to the chemical description on the label. Andrew M. Martin Co., NV Inc., neither makes nor authorizes any agent or representative to make any other warranty or fitness or merchantability, guarantee or representation, express of implied, concerning this material. To the extent consistent with applicable law Andrew M. Martin Co., NV Inc.'s maximum liability for breach of this warranty shall not exceed the purchase price of this product. To the extent consistent with applicable law Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this product which extend beyond the use of the product under normal conditions and in accord with statements made on the label.

#### APPLICATOR TUBE

Front tube panel text: FREEDOM 50% PLUS IGR SPOT ON FOR DOGS

PERMETHRIN INSECTICIDE 50%
PYRIPROXYFEN INSECTICIDE 1.2%

Back tube panel text:

KEEP OUT OF REACH OF CHILDREN

DO NOT USE ON CATS or CAT/SLASH ICON

EPA Reg # 75844-8

Read entire label before each use.

#### ALTERNATIVE MARKETING CLAIMS

[Kills five different kinds of pests on dogs]

[Kills 5 different kinds of pests on dogs]

[Kills five different canine pests]

[Kills 5 different canine pests]

[Kills canine pests belonging to five different orders]

[Kills canine pests belonging to 5 different orders]

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