



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Iain Weatherspoon
Agent for Andrew M. Martin Company
Technology Sciences Group, Inc.
4061 North 156th Drive
Goodyear, AZ 85338

JAN 28 2009

Dear Mr. Weatherspoon:

Subject: Amendment- alternate marketing claims
Freedom 45 plus IGR Spot On for Dogs
EPA Registration Number 75844-7
Your submission dated December 22, 2008

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable with the following comments:

1. On the front panel delete "Kills canine pests belonging to five different orders" and "Kills canine pests belonging to 5 different orders". This is a vague statement.

2. Delete "Contains photostable NyLar ® (ICR*)", "Contains UV stable NyLar ® (ICR*)", "*", "Contains NyLar ® (ICR*), stable in sunlight", "Contains NyLar ® (ICR*), stable to sunlight", "Contains NyLar ® (ICR*), stable to UV light", "Contains an ICR* stable to UV light", "Contains NyLar ® (ICR*) know to be more stable to (in) sunlight than S-methoprene ® and works (lasts) over 30 days longer than S- methoprene ®", "Contains NyLar ® (ICR*) know to be more stable to (in) sunlight, and works (lasts) over 30 days longer than S- methoprene ®", and "Contains NyLar ® (ICR*) know to be much more stable to (in) sunlight, and works (lasts) many weeks longer than S- methoprene ®". Claims relating to product effectiveness may not be false or misleading, and heightened efficacy/comparative claims are not acceptable.

3. After ICR delete the "*". No explanation has been provided to the Agency as what this refers to.

4. Change the EPA Registration Number from "75884-7-81021" to "75844-7".

The Agency still has the following comments cited in the Notice of Registration dated April 1, 2008

a. Since this product is in Acute Toxicity Category IV for all routes of exposure, the Signal Word, Hazards to Humans and First Aid statements are not required. You may delete these statements. Note the Child Hazard Warning is still required.

b. The EPA Registration Number must also appear on the tube label.

27
c. Revise the data matrix by citing the appropriate companion animal safety data.

d. You must generate studies corresponding to guidelines 830.6317 (one year storage stability) and 830.6320 (corrosion characteristics). The observations must be made at 0, 3, 6, 9, and 12 months intervals. The results must be submitted to the Agency along with an electronic copy.

A copy of a stamped label is enclosed for your records.

Sincerely yours,



Richard Gebken
Product Manager (13)
Insecticide Branch
Registration Division (7505P)

Enclosure

3/1
Front panel

FREEDOM 45 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 flea eggs and larvae for up to 6 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]
- [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]

ACTIVE INGREDIENT

Permethrin*[CAS# 52645-53-1]	45.00%
Pyriproxyfen [CAS# 95737-68-1]....	1.00%
OTHER INGREDIENTS	54.00%
TOTAL	100.00%

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

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

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

EPA Registration No. 75844-7-81021
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 0.05 fl oz applicators; 3 x 0.100 fl oz applicators; 2 x 0.200 fl oz; 12 x 0.05 fl oz
8.12 fl oz bottle with dosing gun; 16.23 fl oz bottle with dosing gun.

3 x 1.50 cc applicators; 3 x 3.00 cc applicators; 2 x 6.00 cc applicators; 12 x 1.50 cc applicators
240 cc bottle with dosing gun; 480 cc bottle with dosing gun.

[] alternative or optional verbiage

RECEIVED
JAN 28 2009
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
75844-7

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 1-303-535-4869 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 45 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 1.50cc of FREEDOM 45 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 1.50cc of FREEDOM 45 Plus IGR Spot On For Dogs to the skin of the dog's back between the shoulder blades and 1.50cc to the skin directly in front of the base of the dog's tail.

Package for dogs weighing more than 66 lbs

Apply 3.00 cc of FREEDOM 45 Plus IGR Spot On For Dogs to the skin of the dog's back between the shoulder blades and 3.00 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 1.50 cc of FREEDOM 45 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

6/1

Apply 1.50 cc of FREEDOM 45 Plus IGR Spot On For Dogs (1 tube) to the skin of the dog's back between the shoulder blades and 1.50 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 3.00 cc of FREEDOM 45 Plus IGR Spot On For Dogs (2 tubes) to the skin of the dog's back between the shoulder blades and 3.00 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 1.50 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 or 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 45% PLUS IGR SPOT ON FOR DOGS
PERMETHRIN INSECTICIDE 45%
PYRIPROXYFEN INSECTICIDE 1.0%

Back tube panel text: KEEP OUT OF REACH OF CHILDREN
DO NOT USE ON CATS or CAT/SLASH ICON
EPA Reg # 75844-7
Read entire label before each use.

Further additional marketing claims. () indicates alternative verbiage

Contains photostable Nylar® (IGR*)

Contains UV stable Nylar® (IGR*)

Contains Nylar® (IGR*) , stable in sunlight

Contains Nylar® (IGR*) stable to sunlight

Contains Nylar® (IGR*) stable to UV light

Contains an IGR* stable to UV light

Contains a sunlight stable IGR* Nylar®

Contains an IGR* stable to sunlight

Contains Nylar® (IGR*) known to be more stable to (in) sunlight than S-methoprene® and work (lasts) over 30 days longer than S-methoprene®

Contains Nylar® (IGR*) known to be more stable to (in) sunlight, and work (lasts) over 30

days longer than S-methoprene®

Contains Nylar® (IGR*) known to be much more stable to (in) sunlight, and work (lasts) many weeks longer than S-methoprene®

Nylar® (IGR*) kills flea eggs/larvae/pupae

Nylar® is a registered trademark of McLaughlin, Gormley, King Company

IGR* - Insect Growth Regulator

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