



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 15, 2016

Andrew M. Martin Co., NV Inc.
c/o Nicole O'Loughlin
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Subject: Amended Reregistration Label/Label Amendment – Addition of marketing claims and revisions of directions for use for large and extra-large dogs
Product Name: Freedom 50 Plus IGR Spot On For Dogs
EPA Registration Number: 75844-8
Application Date: 12 May 2016
Decision Numbers: 517341, 413166

Dear Ms. O'Loughlin:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable. The Agency, has also completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the Permethrin RED, and has concluded that your submission is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

NOTE: This product is **not** yet being reregistered under section 4(g) of FIFRA.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated 11/21/2016
- Alternate CSF 1, dated 11/21/2016

A copy of your label stamped "Accepted" is enclosed. This labeling supersedes all previously accepted labeling. Products shipped after 12 months from the date of this amendment or the next printing of the label, whichever occurs first, must bear the new revised label. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40

CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions about this letter, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at Breedon-Alemi.Julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

[Note to reviewer: [Text] in brackets denotes optional text or notes to reviewer.]
[Note to reviewer: {Text} in braces denotes where in the final label text will appear.]

{Front panel - Carton Label}

[Front panel will include picture of dog in the weight range for the product as packaged]

FREEDOM 50 PLUS IGR SPOT ON FOR DOGS

[Font size for word "Dog" in product name will be at least 75% the height of the largest letter in the primary brand name]

FOR USE ONLY ON DOGS [OR] [&] PUPPIES OVER 12 WEEKS OF AGE OR OLDER
For [Puppy/Toy/Miniature] dogs [weighing] 5-10 lbs. [5 to 10 lbs.]
[OR] For [small] dogs [weighing] 11-32 lbs. [11 to 32 lbs.]
[OR] For [large] dogs [weighing] 33-66 lbs. [33 to 66 lbs.]
[OR] For [[extra] [ex-] [large] [XL]] dogs [weighing] more than 66 lbs. [over 66 lbs.]

[Optional Marketing Claims]

Kills, repels [and prevents re-infestation of] fleas for up to 5 weeks
Kills, repels [and prevents re-infestation of] 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
Made in USA [: include depiction of American flag]

[Additional marketing claims – see last page for list of options]

ACTIVE INGREDIENTS

Permethrin* 50.00%
Pyriproxyfen 1.20%

OTHER INGREDIENTS.....48.80%

TOTAL.....100.00%

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

KEEP OUT OF REACH OF CHILDREN
CAUTION

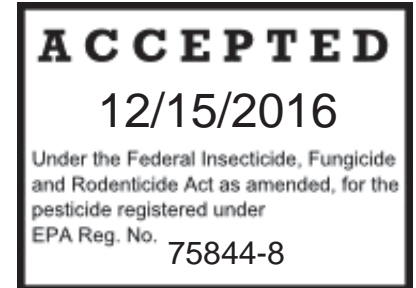
SEE BACK PANEL FOR FIRST AID AND PRECAUTIONARY STATEMENTS
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

EPA Registration No. 75844-8
EPA Establishment No. 75844-CA-02

Package contains a [one] [1] [two] [2] [three]
[3] [four] [4] [six] [6] [eight] [8] [twelve] [12]
month supply
[as applicable]

Net Contents

0.xx fl. oz. (xx [ml][cc]), [1, 2, 3, 4, 6, 8, 12] x 0.xx fl.oz. (xx [ml][cc]) tubes



[1.5 cm x 1.5 cm cat prohibition icon and statement will be in the lower right hand corner of the front panel in a box in yellow with black images]

{Back panel - Carton label}

FREEDOM 50 PLUS IGR SPOT ON FOR DOGS

[any claims listed on the front panel or under "Additional Optional Marketing Claims" may appear on back panel]

PRECAUTIONARY STATEMENTS HAZARDS TO HUMAN 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. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before re-use.

Hazards to Domestic Animals: For external use on dogs only. Do not use on cats or animals other than dogs. Do not treat (use on) dogs or puppies less than 12 weeks of age, weighing less than [insert the lowest weight in range of product as packaged]. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. Sensitivities can occur after ANY pesticide product on dogs. If signs of sensitivity occur, discontinue use, bathe your dog 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: May be toxic or potentially fatal if applied to or ingested by cats. Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none">• 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 by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
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.
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 after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies, or pesticide concerns), you may call the Poison Control Center 1-800-222-1222 twenty four [24] hours per day, seven [7] days per week.	

ENVIRONMENTAL HAZARDS

This product is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run-off into storm drains, drainage ditches, gutters or surface waters. 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.

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. Do not allow children to apply product. Read entire label before use.

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USE RESTRICTIONS

- **DO NOT USE ON CATS OR KITTENS. Do not treat cats or their bedding. This product may be toxic or potentially fatal if applied to or ingested by cats or kittens.**
- Do not apply this product to puppies less than 12 weeks of age, or on dogs weighing less than *[insert the lowest weight in range of product as packaged]*.
- Do not apply this product more than once a month.
- Do not apply more than the specified amount of tubes per dog per treatment.
- Do not allow your dog to ingest this product.

Ready to use, no dilution necessary. Apply this product only as specified on this label. Do not contaminate food or feedstuff.

- Hold tube in upright position pointing away from user's and dog's face and body. Break off tip or cut with scissors. *[optional graphic/photograph/image to illustrate instructions on right]* Apply FREEDOM 50 PLUS IGR SPOT ON FOR DOGS [this product] as follows by gently squeezing the tube.



- Part dog's hair between shoulder blades.

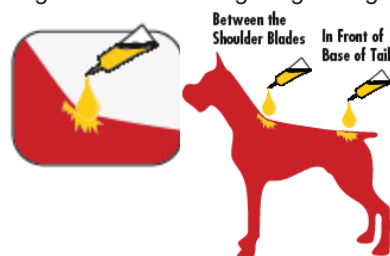
[The following text and a representative pictogram(s) will appear on product packages for the following weight ranges: 5-10 lbs, 11-32 lbs.]

- Apply specified amount of solution to the skin on the dog's back between the shoulder blades as illustrated in the pictogram. SEE DOSING GUIDELINES BELOW.



[The following text and a representative pictogram(s) will appear on product packages for the following weight ranges: 33-66 lbs., over 66 lbs.]

- Apply specified amount of solution to the skin on the dog's back between the shoulder blades and to the skin directly in front of the base of the dog's tail as illustrated in the pictogram. SEE DOSING GUIDELINES BELOW.



[The following directions are for use on puppies/toy/miniature dogs 5-10 lbs. with cartons containing 1, 2, 3, 4, 6, 8, or 12 x 0.7 cc tube(s)]

Do not apply to dogs weighing less than 5 [lbs.] [pounds] or to puppies less than 12 weeks of age. Apply 0.70 [ml][cc] of FREEDOM 50 PLUS IGR SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades.

[The following directions are for small dogs 11-32 lbs. with cartons containing 1, 2, 3, 4, 6, 8, or 12 x 1.33 cc tube(s)]

Apply 1.33 [ml][cc] of FREEDOM 50 PLUS IGR SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades.

[The following directions are for large dogs 33-66 lbs. with cartons containing 1, 2, 3, 4, 6, 8, or 12 x 2.66 cc tube(s)]

Apply 1.33 [ml][cc] of FREEDOM 50 PLUS IGR SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades and 1.33 [ml][cc] to the skin directly in front of the base on the dog's tail.

[The following directions are for extra-large dogs over 66 lbs. with cartons containing 1, 2, 3, 4, 6, 8, or 12 x 5.32 cc tube(s)]

Apply 2.66 [ml][cc] of FREEDOM 50 PLUS IGR SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades and 2.66 [ml][cc] to the skin directly in front of the base on the dog's tail. Do not apply more than one [1] tube per treatment per dog regardless of the dog's weight.

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[Additional packaging option –The below packaging option contains 2, 4, 6, 8, or 12 x 1.33 cc tubes and will be used for large and extra-large dogs]

[The following directions are for large dogs 33-66 lbs.]

Apply 1.33 [ml][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 1.33 [ml][cc] (another 1 tube) to the skin directly in front of the base on the dog's tail.

[The following directions are for extra-large dogs over 66 lbs.]

Apply 2.66 [ml][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 2.66 [ml][cc] (another 2 tubes) to the skin directly in front of the base on the dog's tail. Do not apply more than four [4] tubes per treatment per dog regardless of the dog's weight.

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or the Poison Control Center 1-800-222-1222.

[Side effects box will be located immediately above the cat warning box]



DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

[1.5 cm x 1.5 cm cat prohibition icon and above warning text will appear on the lower right hand corner of the back panel in a box with yellow and black images]

FOR USE ONLY ON DOGS [OR] [&] PUPPIES OVER 12 WEEKS OF AGE OR OLDER *[The previous statement will appear if any of the statements below also appear on the back panel of the label]*

[5-][] to]10 lbs.] [For [Puppy/Toy/Miniature] Dogs 5-][] to]10 lbs.]

[11-][] to]32 lbs.] [For Small Dogs 11-][] to]32 lbs.]

[33-][] to]66 lbs.] [For Large Dogs 33-][] to]66 lbs.]

[More than 66 lbs.] [For XL Dogs over 66 lbs.]

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry (preferably locked) place, away from heat or open flame, in an area that is inaccessible to children and animals.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling (tubes): Nonrefillable container: Do not reuse or refill the tube. If empty: 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.

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 authorized 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 an user acknowledge and assume all risk and liabilities resulting from 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.

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{Side panel #1 & #2 – Carton label}

FREEDOM 50 PLUS IGR SPOT ON FOR DOGS

[One of the following 4 statements will be used on the side panel as appropriate for the weight range of product as packaged:]

[For] [Puppy/Toy/Miniature] dogs 12 weeks of age or older [weighing] 5-10 lbs. [5 to 10 lbs.]

[For] [small] dogs 12 weeks of age or older [weighing] 11-32 lbs. [11 to 32 lbs.]

[For] [large] dogs 12 weeks of age or older [weighing] 33-66 lbs. [33 to 66 lbs.]

[For] [[extra] [ex-] [large] [XL]] dogs 12 weeks of age or older [weighing] more than 66 lbs. [over 66 lbs.]

[any claims listed on the front panel or under “Additional Optional Marketing Claims” may appear on side panel]

{Side panel #3 – Carton label}

FREEDOM 50 PLUS IGR SPOT ON FOR DOGS

[any claims listed on the front panel or under “Additional Optional Marketing Claims” may appear on side panel]

{Side panel #4 – Carton label}

Andrew M. Martin Co., NV Inc.

701 S. Carson St., Suite 200-2808

Carson City, NV 89701

[Barcode]

[Lot][Batch] # _____

{Tube}

FREEDOM 50 PLUS IGR SPOT ON FOR DOGS

[Puppy/Toy/Miniature][Small][Large][Ex-Large]

Permethrin Insecticide 50%

Pyriproxfen Insecticide 1.2%

EPA Reg. No. 75844-8

xx [ml][cc] (0.xx fl. oz.)



DO NOT USE ON CATS – MAY BE FATAL

For dogs [5-][to] 10 lbs.][11-][to] 32 lbs.][33-][to]66 lbs.][more than 66 lbs.][over 66 lbs.]

For dogs 12 weeks or older.

For external use only. [The previous statement will only appear if space on the tube permits]

Read accompanying label before each use.

KEEP OUT OF REACH OF CHILDREN

[Lot][Batch] # _____ [Note to reviewer: Lot # embossed on tube seal]

FREEDOM 50 PLUS IGR SPOT ON FOR DOGS

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[Additional OPTIONAL MARKETING CLAIMS]

[any claims listed on the front panel and below may appear anywhere on the label]

- Kills fleas, ticks, mosquitoes, lice, and mites [on dogs]
- Kills five [5] pests: fleas, ticks, mosquitoes, lice, and mites on dogs
- Kills five [5] canine pests: fleas, ticks, mosquitoes, lice, and mites
- Kills five [5] different kinds of canine pests[!][:] fleas, ticks, mosquitoes, lice, [and] mites
- Kills five [5] different kinds of pests on dogs[!][:] fleas, ticks, mosquitoes, lice, [and] mites
- Kills and repels mosquitoes
- Nylar® (IGR) kills flea eggs/larvae/pupae
- Nylar® is a registered trademark of McLaughlin, Gromley, King Company
- IGR – Insect Growth Regulator
- Prevents re-infestation of fleas [on dogs] for up to 4 weeks [1 month] [30 days]
- Prevents re-infestation of ticks [on dogs] for up to 4 weeks [1 month] [30 days]
- Prevents re-infestation of fleas [on dogs] for up to 5 weeks [35 days]
- Prevents re-infestation of ticks [on dogs] for up to 6 weeks [42 days]
- Kills & repels mites, lice, & mosquitoes for up to 4 weeks
- Puppies/Toy Dogs [For Dogs] 5[-][lbs][to]10 lbs 12 weeks of age or older
- Small Dogs [For Dogs] 11[-][lbs][to]32 lbs 12 weeks of age or older
- Large Dogs [For Dogs] 33[-][lbs][to]66 lbs 12 weeks of age or older
- Ex-Large Dogs [For Dogs] [over] 66 lbs [[&][and] over] 12 weeks of age or older