

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 6, 2012

Mr. James J. McFadden, Ph.D. Regulatory Project Manager Wellmark International 1501 East Woodfield Road, Suite 200 West Schaumburg, IL 60173-5417

Subject:

Amending Labeling; Direct Response to SAL Dated December 22, 2011

RF2102 Fogger M, EPA Reg. No. 2724-808 Your Submission Dated January 17, 2012

Dear Mr. McFadden

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following label revision provision(s):

#### General Comment(s):

- 1. Delete all text throughout the label marked with "strikethrough."
- 2. The inclusion of the words "[NEW formula]" throughout this product label is permitted for a period not to exceed six (6) months from the original date of registration for the subject product. As such, the words "[NEW formula]" must be deleted from this label by no later than June 23, 2012.

Optional Marketing Statements section comment(s), middle of page 1 of 7:

- 3. Revise the 18<sup>th</sup> optional marketing claim to read "[Each [4 oz./3 oz./2 oz.] fogger treats up to [4000/3000/2000] cubic feet (up to [500/375/250] square feet per room)][Multi-room [use] 3 pack][Value Pack]"
- 4. Delete the 25<sup>th</sup> optional marketing claim, since it is considered an implied safety claim.

Directions for Use section comment(s), bottom of page 2 of 7:

5. Revise the subsection heading "GENERAL PRECAUTIONS AND RESTRICTIONS" to read "USE RESTRICTIONS"

Directions for Use section comment(s), top of page 3 of 7:

6. Within the paragraph starting with "[Brand Name][RF2102 Fogger M] reaches ...," revise the 3<sup>rd</sup> sentence to read "Use only one [4 oz.][3 oz.][2 oz.] fogger for each [500 sq. ft.][375 sq. ft.][250 sq. ft.] per room [(25' x 20' area with an 8' ceiling or 4,000 cubic feet.)][(25' x 15' area with an 8' ceiling or 2,000 cubic feet.)] of floor space."

Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA 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 section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists 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 be 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 EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Per 40 CFR §156.10(a)(6), submit one (1) copy of your final printed labeling, incorporating the above changes, before you release the product for shipment. As defined in 40 CFR §152.3, "final printed labeling" means the "label or labeling of the product when distributed or sold." Clearly legible reproductions or photo reductions will be accepted for unusual labels. Note that a clean copy of the master label in most cases does not meet the definition of final printed labeling. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-rnail at <u>Rodia.Carmen@epa.gov</u>.

Sincerely Yours,

Richard J. Gebken

Product Manager (10) Insecticide Branch

Registration Division (7504P)

Enclosure: 002724-008:08 D460023

Label stamped "Accepted with Comments"

#### RF2102 FOGGER M

Contains PRECOR® Insect Growth Regulator, [Plus Etofenprox, an adulticide]

For use in homes [family rooms, great rooms], garages, and kennels, [offices][and enclosed non-

food/feed areas of restaurants, industrial buildings, warehouses, theaters]

Contains [With] PRECOR® [vIGRen®] Insect Growth Regulator [reaches fleas hidden in carpets, rugs,

drapes, upholstery, pet bedding and floor cracks]

Stops hatching eggs [Kills] [flea larvae][from developing into adult fleas] for 210 days [7 months][30 weeks]

7 month protection from fleas [Protects from fleas for 7 months]

Effective long-term control of fleas

Contains an Insect Growth Regulator (IGR) - Kills flea eggs

Kills present [today's] fleas and prevent new [tomorrow's] fleas from growing up to bite

[Also] Kills [Controls][adult] fleas and [pre-adult fleas] [including] their hatching flea eggs [flea larvae],

[Also] Kills ticks, cockroaches, ants, spiders, mosquitoes & silverfish

Kills fleas [plus][+] [kills][hatching] eggs

Kills fleas you see and those you don't

Leaves no lingering odor [bad smell] or stains [no sticky mess]

Non-Staining, Easy to apply

Effectively breaks the flea life cycle

Prevents flea reinfestation and flea build-up for 210 days [7 months][30 weeks]

Inhibits [Controls] flea reinfestation for up to [210 days [30 weeks][7 months]

[Each fogger treats up to [4000/3000/2000] cubic feet (up to [500/375/250] sq ft)][Multi-room [use] 3 pack][Value Pack]

[Water based] [NEW formula]

Contains no CFC or other ozone-depleting substances. Federal regulations prohibit CFC propellants in aerosols.

Economical Do-It-Yourself Flea Control

Kills Exposed or Accessible Stages of these Insects: Ants, Carpet Beetles, Cockroaches, Confused Flour Beetles, Crickets, Earwigs, Firebrats, Fleas, Flies, Fruit Flies, Hornets, House Flies, Mosquitoes, Pillbugs, Saw-Toothed Grain Beetles, Silverfish, Sowbugs, Spiders, Stable Flies, Wasps, and Yellow Jackets Optional Spanish note: For instructions and warranty in Spanish, see inside of carton.

If you do not have a carton, call 1-800-XXX-XXXX.

25 Sold by veterinarians for over 30 years

#### **ACTIVE INGREDIENTS:**

(S)-Methoprene (CAS #65733-16-6)	0.09%
Etofenprox (CAS #80844-07-1)	
Tetramethrin (CAS #7696-12-0 )	
N-octyl Bicycloheptene Dicarboximide (CAS #113-48-4)	
OTHER INGREDIENTS:	
TOTAL	100.00%

## KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for additional Precautionary Statements

EPA Reg. No. 2724-808

EPA Est. No.

Net Contents: [4 oz/3 oz/2 oz][not for individual sale]

ACCEPTED
With COMMENTS
In EPA Letter Dated:

Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

2724-808

# PRECAUTIONARY STATEMENTS HAZARD TO HUMANS & DOMESTIC ANIMALS CAUTION

Causes moderate eye irritation. Repeated exposure to etofenprox can cause skin irritation. Avoid contact with eyes, skin, or clothing. Breathing spray mist may be harmful. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID	
IF IN EYES:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes,</li> </ul>
	<ul><li>then continue rinsing eye.</li><li>Call a poison control center or doctor for treatment advice.</li></ul>

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.

#### PHYSICAL OR CHEMICAL HAZARDS



#### Extremely Flammable Ingredient Ingrediente Extremadamente Inflamable

Flammable. This product contains a highly flammable ingredient. It may cause fire or explosion if not used properly. Follow the Directions for Use on this label carefully. Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F. may cause bursting.

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

READ THE ENTIRE LABEL PRIOR TO USE. USE STRICTLY IN ACCORDANCE WITH ALL LABEL PRECAUTIONS AND DIRECTIONS.

INSTRUCCIONES EN ESPAÑOL DENTRO DE LA CAJA

#### **GENERAL PRECAUTIONS AND RESTRICTIONS**

Wait two (2) hours after application, then open windows, vents, and doors for two hours. If an odor is still detected, additional ventilation is required.

Remove or cover exposed food and drinking water before application.

Remove or cover dishes, utensils, food processing equipment, and food preparation surfaces, or wash them before use.

[Brand Name] RF2102 Fogger M kills adult fleas, hatching flea eggs, flea larvae, and ticks [houseflies, gnats, cockroaches, carpet beetles, ants, spiders, flying moths, clothes moths, mosquitces, silverfish, sawtoothed grain beetles, rice weevils, pill bugs, crickets, confused flour beetles, wasps, hornets, and palmetto bugs]. Does not control bedbugs. PRECOR® (vIGRen®) Insect Growth Regulator, the ingredient in [Brand Name], provides 7 months' [210 days'][30 weeks'] protection by preventing flea eggs from ever developing into biting fleas. This [Brand Name] product enables you to fill an entire room with insect-killing fog while you are away. For best results, use [Brand Name] fogger together with other [Brand Name] products for complete control of fleas.

[Brand Name][RF2102 Fogger M] reaches fleas hidden in carpets, rugs, drapes, upholstery, pet bedding, and floor cracks. For best results, treat entire dwelling with particular attention to kitchens and bathroom areas. Use only one fogger for each [500 sq. ft.][375 sq ft][250 sq. ft.](25' x 20' area with an 8' ceiling or 4,000 cubic feet)(25' X 15' area with an 8' ceiling or 3,000 cubic feet)(25' X 10' area with an 8' ceiling or 2,000 cubic feet) of floor space.

NOTE: Schools, transportation facilities and hospitals/nursing homes are not use sites on label) [For Commercial/Occupational use] For use in the non-food and non-feed areas of food and feed handling establishments. Do not use in food or feed areas of food or feed handling establishments, restaurants or other areas where food or feed is commercially prepared or processed. Do not use in serving areas while food is exposed or the facility is in operation. Serving areas are areas where prepared foods are served, such as dining rooms but excluding areas where foods may be prepared or held. Remove food from food serving areas of commercial establishments prior to treatment. Wash all exposed food serving/handling surfaces thoroughly with water following treatment and before use. Non-food and non-feed areas of food and feed establishments are areas such as garbage rooms, lavatories, vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets and storage (after canning and bottling). Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

#### SHAKE WELL BEFORE USING

#### TO USE THIS PRODUCT CORRECTLY

EPA PRE-APPROVED PICTOGRAM 1 REPRESENTING - ) DO NOT USE MULTIPLE FOGGERS PER ROOM. EPA PRE-APPROVED PICTOGRAM 2 REPRESENTING - ) DO NOT USE IN SMALL ENCLOSED SPACES SUCH AS CLOSETS, CABINETS OR UNDER COUNTER OR TABLES. USE OF A FOGGER IN AN ENCLOSED SPACE MAY CAUSE THE PRODUCT TO EXPLODE, RESULTING IN INJURY TO PEOPLE OR DAMAGE TO PROPERTY. DO NOT USE IN A ROOM 5 FT. X 5 FT. OR SMALLER; INSTEAD, ALLOW FOGS TO ENTER FROM OTHER ROOMS.

**FOR CONSUMER USE**: Do not apply this product in a way that will contact adults, children, or pets, either directly or through drift.

#### BEFORE YOU FOG

Vacuum thoroughly before fogging. To ensure unobstructed flow of fogger mist, OPEN cabinets, cupboards, drawers, closets and doors in areas to be treated.

EPA PRE-APPROVED PICTOGRAM 5 REPRESENTING - ) REMOVE or cover exposed foods, dishes, cooking utensils, food-processing equipment and surfaces. REMOVE pets and birds; COVEP, and turn off air flow systems in aquariums. REMOVE or COVER childrens' and pets' toys. COVER waxed wood floors and waxed wood furniture in the immediate area surrounding the fogger (newspaper may be used). CLOSE outside doors and windows. SHUT OFF fans and air conditioners and temporarily disconnect smoke alarms.

EPA PRE-APPROVED PICTOGRAM 3 REPRESENTING - ) UNPLUG AND TURN OFF ALL IGNITION SOURCHES, SUCH AS PILOT LIGHTS (SHUT OFF GAS VALVES), OTHER OPEN FLAMES, or other running electrical appliances that cycle off and on (i.e., refrigerators, thermostats, etc.). EPA PRE-APPROVED PICTOGRAM 4 REPRESENTING - ) NO FLAMES OR PILOT LIGHTS. Call your gas utility or management company if you need assistance with your pilot lights.

DO NOT use fogger in a cabinet or under a counter or table.

Place a chair, table or stand in the center of the room to be fogged. Cover with several layers of newspaper or paper towels.

#### TO START FOGGING

SHAKE WELL BEFORE USING. Before activating, tilt sprayer AWAY from face (fogger sprays up). Press down firmly on edge of actuator tab until it locks into place. Do not inhale the spray mist. Set fogger on chair covered with newspapers or paper towels and leave the premises immediately.

Vacate the treated house, individual apartment unit, or other structure immediately. KEEP TREATED AREA CLOSED. DO NOT RE-ENTER FOR AT LEAST TWO HOURS. Keeping treated area sealed for a longer period will enhance fogger performance. Use enclosed Door Hang Tag to mark the time when reentry is permitted (at least two hours after the start time).

[Door Hang Tag Text]

"Fill out and place hang-tag on the door to the treated area to alert family and others with access to the treated area not to enter for X hours."

Do not enter until [space for time] on [space for date].

[Brand Name][Product Name] Treatment.

[This room is currently being treated by (Brand Name)]

[Another room protected by (Brand Name)]

[(Brand Name) treatment underway]

#### AFTER FOGGING

**Do Not Re-enter for 2 Hours.** (Clock pictogram with shaded entry restriction). (EPA PRE-APPROVED PICTOGRAM 6 REPRESENTING - ) Air out the room before entering.

AIRING OUT: BEFORE REOCCUPYING THE AREA, OPEN ALL DOORS AND WINDOWS, TURN ON AIR CONDITIONER AND FANS AND ALLOW TREATED AREA TO AIR OUT FOR TWO HOURS.

Do not allow children or pets to contact treated surfaces until spray has dried.

Turn on all pilot lights and appliances, smoke alarms, and aquariums that were turned off. For best results, spot treat with [Brand Name] premise products under beds, furniture, or obstructed areas where fogger mist may not penetrate.

NOTE: When treating for fleas or ticks, clean and treat pet sleeping areas. Also treat dogs and cats with a flea control product registered for use on pets before allowing them to re-enter the treated areas.

STORAGE and DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. (for occupational use only) STORAGE: Store in a cool, dry area away from heat or open flame.

DISPOSAL: Do Not Puncture or Incinerate! If empty: Place in trash or offer for recycling if available.

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

For more information [about {Brand Name} products][about flea and tick problems and how to solve them] or in case of emergency, call 1-800 XXX XXXX [weekdays from][time]. [Unconditional money back guarantee][Satisfaction Guaranteed or your money back][In case of emergency or for product use information, call (phone number): (URL)][If not completely satisfied with this product, return it to place of purchase with your receipt for a full refund.]

#### WARRANTY STATEMENT

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages

PRECOR®, vIGRen® Insect Growth Regulator, and ZODIAC®, are registered trademarks of Wellmark International.

Wellmark International 1501 E. Woodfield Rd. 200W Schaumburg, IL 60173 [URL] Made in USA

Wellmark International confirms that the Spanish language text is/will be a true and accurate translation of the English text.

[Optional marketing information: one of following options to be used)

Flea Life Cycle graphic: Eggs/Larvae/Pupae/Adult Flea

#### IMPORTANT INFORMATION ABOUT FLEA CONTROL

[3 Steps]

To minimize flea infestation, it is necessary to treat not only your pets, but also their surrounding environment. [Brand Name] products have been formulated to work together well with other [Brand Name] products. For best results, simply follow these three easy steps:

#### STEP 1 - TREAT YOUR PET

\* Apply a topical or Shampoo, Dip or Mousse to your pet to kill biting adult fleas on your pet.

\* [Brand Name] products in Step 1 kill adult fleas and flea eggs with a combination of an adulticide and PRECOR [VIGREN] Insect Growth Regulator.

#### STEP 2 - PROTECT YOUR PET

Collar your pet to provide long-lasting protection.

\* This collar kills biting adult fleas.

\* Use[Brand Name] flea spray to provide quick kill of fleas your pet picks up on outings.

#### STEP 3 - TREAT YOUR HOME

 Treat indoors [premises] and outdoors with [Brand Name] products to protect your entire home and guard against flea reinfestation.

• [Brand Name] products in Step 3 kill biting adult fleas and flea eggs using a combination of an adulticide and PRECOR [VIGREN] Insect Growth Regulator.

#### IMPORTANT INFORMATION ABOUT FLEA CONTROL

[4 Steps]

To minimize flea infestation, it is necessary to treat not only your pets, but also their surrounding environment. [Brand Name] products have been formulated to work together well with other [Brand Name] products. For best results, simply follow these four easy steps:

#### 1 - Shampoo or Dip your pet

\* A Shampoo, Dip or Mousse will kill biting adult fleas on your pet.

[Brand Name] products in Step 1 kill adult fleas and flea eggs with a combination of an adulticide and PRECOR [VIGREN] Insect Growth Regulator.

#### 2 - Place a Collar on your pet

A [Brand Name] Collar will provide long-lasting protection.

\* This collar kills biting adult fleas.

#### 3 - Treat the areas your pet frequents

All [Brand Name] products in Step 3 contain PRECOR [VIGREN] Insect Growth Regulator. Use a
[Brand Name] Aerosol, Fogger or Spray to kill adult fleas and flea larvae in your vard.

 Follow individual product directions to kill additional fleas which may later emerge from protected cocoons.

#### 4 - Maintain your flea-free pet

· Use a [Brand Name] On-Animal Spray to kill any fleas your pet picks up on outings.

• [Brand Name] products in Step 4 kill adult fleas and flea eggs using a combination of an adulticide and PRECOR [VIGREN] Insect Growth Regulator. [optional marketing label text for Hartz:

Important Information: The A B C's of Flea Control [Management]

A Treat Your Pet with {Brand Name} to kill fleas and ticks [living on your pet] while conditioning your dog's coat.

- B Protect Your Pet with {Brand Name} to keep fleas and ticks from reinfesting your pet. For continuous protection, use {Brand Name}.
- C Treat Your Home with {Brand Name} containing VIGREN, an insect growth regulator (IGR). Both are guaranteed to kill fleas and ticks plus protect your home from reinfestation of hatching flea eggs for 210 days.

Be sure to read full directions and precautions on the label of each product you use.]

[{Brand Name} products are designed to work together in a complete insecticidal system. For [elimination] total control of fleas, it is necessary to treat not only the pet but also its surrounding environment. Use {Brand Name} products to follow these simple ABC's for control [to get rid] of fleason your pet and around your home.

- A TREAT YOUR PET with one of the {Brand Name} on-animal products such as {Brand Name}. Use a {Brand Name} product containing VIGREN, an Insect Growth Regulator (IGR), to also stop hatching flea eggs from developing into biting adults.
- B PROTECT YOUR PET with a {Brand Name} repellant or flea and tick collar to keep fleas and ticks from reinfesting your pet. The {Brand Name} collar with VIGREN IGR will also prevent flea eggs from hatching.
- C TREAT YOUR HOME, both indoors and outdoors, with {Brand Name} home spray or fogger, both with VIGREN IGR and {Brand Name} yard spray to protect your entire home and guard against flea reinfestation.

Be sure to read full directions and precautions on the label of each product you use.]