

2724-493

9/23/2008

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



OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

SEP 23 2008

James McFadden
Wellmark International
1501 E. Woodland Rd., Suite 200W
Schaumburg, IL 60173

Dear Dr. McFadden:

Subject: Label amendment in response to propoxur RED and efficacy DCI
RF-2007 Collar
EPA Registration No. 2724-493
Submission Date: December 12, 2007

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided you make the following changes before you release the product for shipment bearing the amended labeling:

- Revise the warranty statement so it reads, "**To the extent consistent with applicable law, Seller makes no warranty...**"
- **NOTE:** Should you wish to add/retain a reference to the company's website on your label, the website then 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 Assurance.

- Delete the following claims:

- “PRECOR [vIGRen®] is Prevention of fleas”
- “Kills Flea Eggs to [help eliminate][prevent][flea][infestation] [reinfestation][of your home] for up to [5 months][150 days]”
- “Ring of Prevention [Protection] to prevent flea build-up in your home or on your pets”
- “Temporary Wetting will not impair effectiveness”
- “[Ovicidal] - kills flea eggs [before they hatch] for up to [150 days][5 months]”
- “Prevents flea build-up by killing fleas on your pet and flea eggs before they hatch in your home”
- “Kills [adult] fleas before they infest your home”
- “Waterproof [Works even when wet]”
- “Specially formulated for dogs/puppies”
- “Kills [deer] ticks (including *Ixodes scapularis*), which may transmit Lyme disease [*borreliosis*] [the major carrier of human and canine Lyme disease]”
- “Effective against ticks [vectors, deer ticks, *Ixodes scapularis*] which may transmit Lyme disease [*borreliosis*]”
- “Controls [Kills] Lyme disease [*borreliosis*]-carrying ticks, Brown Dog Ticks (*Rhipicephalus sanguineus*), American Dog Tick (*Dermacentor variabilis*), Lone Star Tick (*Amblyomma americanum*), Deer Ticks (*Ixodes scapularis*)”
- “Kills [ticks][including those that may transmit Lyme disease][Brown Dog Ticks][American Dog Tick][Lone Star Tick][Deer Ticks][which may carry Lyme disease] for up to [5 months][150 days]”
- “Kills tick species [common to dog] including: Brown Dog Tick (*Rhipicephalus sanguineus*), American Dog Tick (*Dermacentor variabilis*), Lone Star Tick (*Amblyomma americanum*), Rocky Mountain Wood Tick (*Dermacentor variabilis* or *andersoni*), Deer Tick (*Ixodes scapularis* or *dammini*)”
- “Collar does not need replacement if dog/puppy becomes wet”
- “This collar begins working to kill fleas, ticks, and flea eggs as soon as it is placed around the dog’s/puppy’s neck”
- “Protects your pet”
- “One step hassle free protection”
- “Complete protection [collar] against [fleas][all stages of the flea life”

- **Revise the following claims:**

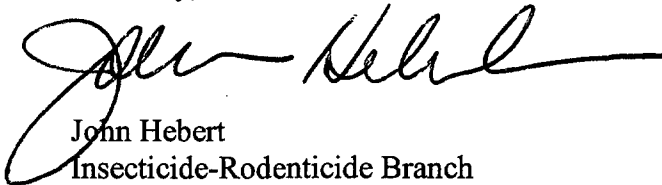
- “Contains an Insect Growth Regulator to prevent flea development” to “Contains an Insect Growth Regulator to prevent adult flea development”
- “Controls][Kills] [Prevents] [Helps eliminate] [adult] Fleas” to “Controls][Kills] [adult] Fleas”
- “ [Controls][Kills][Lasts][Works][Protects][Helps Eliminates] up to [150 days][5 months]” to “Controls][Kills][Lasts][Works][Protects] up to 4 months.”
- “Kills [adult fleas][ticks][flea eggs] & [flea larvae] for up to [5 months][150 days]” to “Kills [adult fleas][ticks] for up to [4 months][120 days]”
- “Effectively [controls][stops][prevents] flea infestations, Helps [prevent][eliminate] tick infestations” to “Effectively controls flea infestations.”
- “Kills [adult][fleas][to] Prevents infestations [and reinfestations][on your pet] for up to [5 months][150 days]” to “Kills [adult][fleas]][on your pet] for up to [4 months][120 days]”
- “Up to [150 days][5 months] protection [control of] against [immature and adult] fleas and flea eggs” to “Up to [120 days][4 months] protection [control of] against adult fleas.”
- “Up to [150 days][5 months] protection [control of] against ticks” to “Up to [120 days][4 months] protection [control of] against ticks”
- “[Long Lasting][Protection][Relief] up to [5 months][150 days]” to “[Protection][Relief] up to [4 months][120 days]”
- “[Helps] Eliminates [stops][prevents] major [primary][main] source of home infestation by killing [controlling] fleas and ticks on your pet, helps [prevent][eliminate] ticks” to “[Helps] [stops] major [primary][main] source of home infestation by killing [controlling] fleas and ticks on your pet.”
- “Prevents flea reinfestation for up to (5 months)(150 days)” to “Controls flea reinfestation for up to (4 months)(120 days)”
- “[Prevents][Kills] all [flea] stages of the flea life cycle” to “[Kills] [adult fleas] and stops adult flea emergence.”
- “Stops and prevents infestations on your pet for up to [5 months][150 days]” to Stops infestations on your pet for up to [5 months][150 days]
- “[5 months][150 days] Dual Action [formula] Collar” to “up to [4 months][120 days] Dual Action [formula] Collar”
- “Kills immature and adult fleas and flea eggs for up to [5 months][150 days]” to “Kills adult fleas and prevents adult fleas from emerging from eggs for up to [4 months][120 days]”

- “Kills ticks for up to [150 days][5 months]” to “Kills ticks for up to [120 days][4 months]”
- “Collar gives up to [150 days][5 months] protection” to “Collar gives up to [120 days][4 months] protection.”
- “Replace in [150 days][5 months] for continuous protection from adult fleas, ticks, and flea egg[s]” to “[Replace in [120 days][4 months] or sooner for continuous protection from adult fleas, ticks, and adult flea emergence from eggs.”
- “This [brand name] collar is designed to kill adult fleas, ticks, and flea eggs over the entire pet” to “This [brand name] collar is designed to kill adult fleas, ticks and prevent adult flea emergence over the entire pet.”
- “This collar will provide continuous protection against fleas, ticks, and flea eggs [hatch] for up to [5 months][150 days]” to “This collar will provide continuous protection against fleas and ticks, and prevents adult flea emergence for up to [4 months][120 days].”
- “Replace collar every [5 months][150 days] to help control adult flea and tick” to “Replace collar every [4 months][120 days] or sooner to help control adult flea and brown dog ticks.”

Approval of this labeling amendment does not constitute approval of your application for reregistration of this product. Product reregistration is currently pending and future labeling amendments and/or additional data may be required.

You must submit one (1) copy of the final printed label before you release the product for shipment. Products shipped after 12 months from the date of this Notice or the next printing of the label whichever occurs first, must bear the new revised label. A stamped copy of the label is enclosed for your records. Should you have any questions, please contact Julie Chao at 703-308-8735 or chao.julie@epa.gov.

Sincerely,



John Hebert
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

5049

[] indicates optional statements

RF-2007 COLLAR

(FRONT OR BACK PANEL)

ACTIVE INGREDIENTS:

Propoxur (CAS #114-26-1) 10.0%

(S)-Methoprene (CAS # 65733-16-6)..... 2.1%

OTHER INGREDIENTS:..... 87.9%

Total: 100.0%

DO NOT ALLOW CHILDREN TO PLAY WITH THIS COLLAR

CAUTION

See back panel for [Ingredients and] additional Precautionary Statements

EPA Reg. No 2724-493

EPA Est. No.

Net Weight:

ACCEPTED
With COMMENTS
In EPA Letter Dated:
SEP 23 2008

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

2724-493

MARKETING CLAIMS

For use only on dogs/puppies

[Contains][Plus] with PRECOR® [vIGRen®] Insect Growth Regulator [IGR]

Contains an Insect Growth Regulator (IGR) to prevent flea development

Kills Flea Eggs to [help eliminate][prevent][flea][infestation][reinfestation][of your home] for up to [5 months][150 days]

[Controls][Kills] [Prevents] [Helps eliminate] [adult] Fleas

[Controls][Kills][Lasts][Works][Protects][Helps Eliminates] up to [150 days][5 months]

Contains an adulticide [to kill adult fleas and ticks]

Kills [adult fleas][ticks][flea eggs] & [flea larvae] for up to [5 months][150 days]

Effectively [controls][stops][prevents] flea infestations, Helps [prevent][eliminate] tick infestations

Kills [adult][fleas][to] Prevents infestations [and reinfestations][on your pet] for up to [5 months][150 days]

Up to [150 days][5 months] protection [control of] against [immature and adult] fleas and flea eggs

Up to [150 days][5 months] protection [control of] against ticks

PRECOR [vIGRen®] is Prevention of fleas

[Long Lasting][Protection][Relief] up to [5 months][150 days]

Ring of Prevention [Protection] to prevent flea build-up in your home or on your pets

PRECOR [vIGRen] breaks [stops] the flea life cycle

Works From Head to Tail

Kills fleas and ticks

Satisfaction Guaranteed or your money back

Temporary wetting will not impair effectiveness

[Ovicidal] - kills flea eggs [before they hatch] for up to [150 days][5 months]

Prevents flea build-up by killing fleas on your pet and flea eggs before they hatch in your home

Kills [adult] fleas before they infest your home

[Helps] Eliminates [stops][prevents] major [primary][main] source of home infestation by killing [controlling] fleas and ticks on your pet, helps [prevent][eliminate] ticks

Kills [adult] fleas which may cause flea bite anemia

Kills [adult] fleas which may cause flea allergy dermatitis

Kills [adult] fleas which may transmit tapeworms

Prevents flea reinfestation for up to (5 months)(150 days)

For use on [small][medium][large] dogs/puppies [with necks up to (#)][of all sizes]

Collar can be fitted for all dogs

[Unique one-piece buckle design][Integrated one-piece buckle]

[Integrated plastic buckle][Expandable Collar][Stretch Band]

Kills [deer] ticks (including *Ixodes scapularis*), which may transmit Lyme disease [*borreliosis*] [the major carrier of human and canine Lyme disease]

Effective against ticks [vectors, deer ticks, *Ixodes scapularis*] which may transmit Lyme disease [*borreliosis*]

Controls [Kills] Lyme disease [*borreliosis*]-carrying ticks, Brown Dog Ticks (*Rhipicephalus sanguineus*), American Dog Tick (*Dermacentor variabilis*), Lone Star Tick (*Amblyomma americanum*), Deer Ticks (*Ixodes scapularis*)

Kills [ticks][including those that may transmit Lyme disease][Brown Dog Ticks][American Dog Tick][Lone Star Tick][Deer Ticks][which may carry Lyme disease] for up to [5 months][150 days]

Kills tick species [common to dog] including: Brown Dog Tick (*Rhipicephalus sanguineus*), American Dog Tick (*Dermacentor variabilis*), Lone Star Tick (*Amblyomma americanum*), Rocky Mountain Wood Tick (*Dermacentor variabilis* or *andersoni*), Deer Tick (*Ixodes scapularis* or *dammini*)

[Prevents][Kills] all [flea] stages of the flea life cycle

Stops and prevents infestations on your pet for up to [5 months][150 days]

[5 months][150 days] Dual Action [formula] Collar

Protects your pet

Professional Brand pet care products

Experience in serving the veterinarian and pet supply industry for over 30 years

One step hassle free protection

Complete protection [collar] against [fleas][all stages of the flea life cycle]

Kills immature and adult fleas and flea eggs for up to [5 months][150 days]

Kills ticks for up to [150 days][5 months]

Waterproof [Works even when wet]

Specially formulated for dogs/puppies

Collar gives up to [150 days][5 months] protection

[Descriptor] Blue/Green/Red/Black Collar

7099

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS AND PUPPIES 12 WEEKS OF AGE AND OLDER**

DIRECTIONS FOR USE:

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

1. Buckle collar around dog's/puppy's neck. [Thread flat end of the collar through buckle hole and tighten as necessary, so that at least two ridges are covered by the buckle. Since the plastic buckle is molded into the collar, the possibility of neck irritation and buckle failure is reduced.] Collar should fit snug enough to prevent placement of the dog's/puppy's leg or lower jaw through the collar, yet loose enough to be rotated about the neck.
2. Leave 1-2 extra inches on the length of the collar for adjustment, cut off excess, and dispose of in trash.
3. Check periodically and adjust fit if necessary, especially when puppies are rapidly growing.
4. Replace in [150 days][5 months] for continuous protection from adult fleas, ticks, and flea egg[s] [hatch]. [To release the collar, squeeze buckle between thumb and finger and pull sharply.] Collar does not need replacement if dog/puppy becomes wet.

To minimize flea infestation use appropriate [other {Brand Name} flea and tick] products to:

1. Treat the indoor environment, especially where pets spend time resting
2. Treat the outdoor environment when necessary

STORAGE and DISPOSAL: **Storage:** Store in original unopened package away from children.
Disposal: Dispose of in trash. Collar should be left in place once fitted on dog/puppy. If collar is temporarily removed, wrap in paper or plastic; do not allow children to have access to collar.

WHAT TO EXPECT:

For Fleas and Ticks:

1. This [brand name] collar is designed to kill adult fleas, ticks, and flea eggs over the entire pet.
2. This collar begins working to kill fleas, ticks, and flea eggs as soon as it is placed around the dog's/puppy's neck.
3. This collar will provide continuous protection against fleas, ticks, and flea eggs [hatch] for up to [5 months][150 days].
4. Dead ticks will fall off or may be easily removed.
5. Replace collar every [5 months][150 days] to help control adult flea and tick infestations on your pet and in your home or if the adult flea problem is under control but flea build-up protection is desired.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS-

CAUTION: Do not get dust or collar in mouth. Harmful if swallowed or absorbed through skin. Do not get dust in eyes, will cause temporary constriction of the pupils*. The dust released by this collar is a cholinesterase inhibitor. Avoid contact with skin, eyes or clothing.

Humans: Do not open package until ready to use. Do not allow children to play with this collar. Pesticidal dust will form on this collar during storage. Wash hands thoroughly with soap and water after handling collar.

Animals: Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing dogs. Do not use on puppies under 12 weeks of age. Do not use this product on dogs/puppies simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting** drugs or pesticides (e.g. carbaryl or tetrachlorvinphos, etc.). However, flea and tick collars may be immediately replaced. When collar is first worn, observe neck area every few days for irritation. Remove collar at the first sign of irritation or adverse reaction. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your dog/puppy with mild soap and rinse with large amounts of water.

FIRST AID	
Call a poison control center or doctor for treatment advice	
If swallowed	<ul style="list-style-type: none"> • Call 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 do so by the 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.
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, if present, after the first 5 minutes, then continue rinsing eye.
IN CASE OF EMERGENCY, CALL [PHONE NUMBER] OR A POISON CONTROL CENTER. Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
NOTE TO PHYSICIAN/VETERINARIAN: Contains an N-methyl carbamate that inhibits cholinesterase. *Atropine is antidotal only if symptoms of cholinesterase inhibition are present.	

9099

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and handling of this material when such use and handling are contrary to label instructions.

Wellmark International
Schaumburg, Illinois 60173

Satisfaction guaranteed or your money back. Call [phone number] or visit our Web site [internet address] for additional product use information.

**For information on cholinesterase inhibition please call our 800 number or consult your veterinarian.

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Made in USA