

2724-491

1/28/2010

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAN 28 2010

Ms. Nancy Huebl
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173

Subject: Revision to Add Headers to Clarify Collar

Dear Ms. Huebl:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated December 15, 2009 for:

EPA Registration 2724-491

Wellmark International RF 9907 Flea Collar for Cats & Kittens

The Registration Division (RD) has conducted a review of this request for applicability under PRN 98-10 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, call me at 703 305-5409 or electronically at daniel.dani@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Dani Daniel".

Dani Daniel
Registration Division (7505P)
Insecticide/Rodenticide Branch



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

NOTIFICATION

1. Company/Product Number Wellmark International/2724-491	2. EPA Product Manager John Hebert	3. Proposed Classification JAN 28 2010 <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF 9907 Flea Collar for Cats & Kittens	PM # 7	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application

Notification - Explain below. Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Notification to add "For Fleas" and "For Ticks" header to existing approved DFU for clarification of 8 & 6 month collar replacement intervals. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 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 <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container 0.2-1.5 oz 1	If "Yes" Unit Packaging wgt. No. per container

3. Location of Net Contents Information: Label Container

4. Size(s) Retail Container: 0.2 - 1.5 oz.

5. Location of Label Directions: On Label On Label Accompanying Product

6. Manner in Which Label is Affixed to Product: Lithograph Paper glued Stenciled Other printed on cardboard

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Nancy Huebl	Title Senior Registration Specialist	Telephone No. (Include Area Code) (847) 330-5376
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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

2. Signature: *Nancy Huebl*

3. Title: Senior Registration Specialist

4. Typed Name: Nancy Huebl

5. Date: 15-Dec-09

6. Date Application Received (Stamped)

Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173
847 330 5300
www.wellmarkinternational.com

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Wellmark

December 15, 2009

Document Processing Desk (AMEND)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900 One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: J. Hebert, PM 7

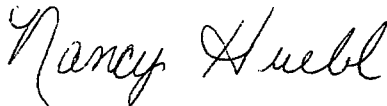
SUBJECT: LABEL NOTIFICATION
REVISION TO ADD HEADERS TO CLARIFY COLLAR
REAPPLICATION FOR FLEAS/TICKS
FOR RF-9907 FLEA COLLAR FOR CATS & KITTENS/EPA REG. NO. 2724-491

Dear Mr. Hebert:

Enclosed is a completed EPA Form 8570-1 and 1 copy of revised labeling for the above product. New text is highlighted in red. The label cover sheet details the change. The purpose of this notification is to add "For Fleas" and "For Ticks" to the two sentences in the existing approved DFU text (No. 4) indicating "reapply collar at 8 months" and "reapply collar at 6 months". The 8 months is related to fleas and the 6 months is related to ticks. No other changes were made to the label.

If you have any questions or if I can provide any further assistance, please, call me directly at 847/330-5376. Thank you for your assistance in this matter.

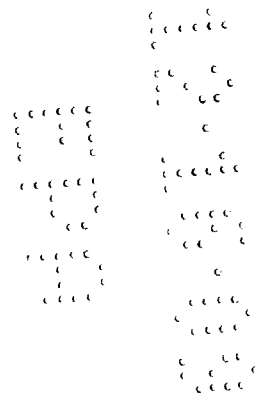
Yours sincerely,
WELLMARK INTERNATIONAL



Nancy Huebl
Sr. Registration Specialist
nhuebl@central.com

enclosure

cc: J. McFadden/C. Elmi/H. Friedli/C. Purcell



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NOTIFICATION

JAN 28 2010

[] indicates optional statements

RF-9907 FLEA COLLAR FOR CATS & KITTENS

**Alternate brand Names: ZODIAC® Flea & Tick Collar for Cats,
ZODIAC® Flea & Tick Collar for Cats & Kittens,
ZODIAC® Breakaway® Flea & Tick Collar for Cats & Kittens
VET KEM® Breakaway® Plus Flea & Tick Collar for Cats**

with [Plus] PRECOR® [vIGRen®] Insect Growth Regulator [IGR][Kills flea eggs]

Kills [Adult] Fleas & Ticks

Up to [245 days][35 weeks][8 months] protection [control of] against immature and adult fleas and flea eggs

Up to [175 days][25 weeks][6 months] protection [control of] against ticks

Works in as little as [24 hours][1 day]

[Available through veterinarians]

PRECOR [vIGRen] breaks the flea life cycle

Works From Head to Tail [to kill fleas for up to 8 months and ticks for up to 6 months]

Satisfaction 100% Guaranteed or your money back

[Ovicidal] - kills flea eggs [before they hatch] for up to [245 days][35 weeks][8 months]

Kills fleas and kills flea eggs

For cats of all sizes

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

[Unique breakaway design]

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

Effective against ticks

Kills immature [fleas] and adult fleas and flea eggs up to [35 weeks][245 days][8 months]

Flea protection for up to 8 months

Kills ticks up to [175 days][25 weeks][6 months]

(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

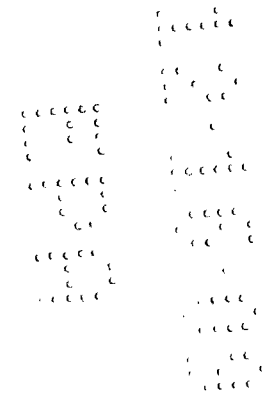
CAUTION

See Precautions on back

EPA Reg. No 2724-491

Net Weight:

EPA Est. No.



**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON CATS AND KITTENS 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 cat's neck. [Thread flat end of the collar through buckle hole and tighten as necessary, so that at least 2 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.] Fit collar snug enough to prevent placement of the cat'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 kittens are rapidly growing.
4. **For Fleas:** Replace in [245 days][35 weeks][8 months] or sooner if needed. **For Ticks:** Replace in [175 days][25 weeks][6 months] or sooner if needed. [To release the collar, squeeze buckle between thumb and finger and pull sharply.] Collar does not need replacement if cat becomes wet.

[UNIQUE FEATURE: This collar is designed to stretch under the weight of an average sized adult cat. It helps the cat to free itself ("breakaway") if the collar gets snagged on a fixed object. If the collar is fitted improperly, so that it is loose enough for a cat to work the collar over its leg or jaw, this release feature may not stretch adequately to allow the extra room necessary for the cat to free itself.]

To minimize flea infestation use appropriate products to:

1. Treat the pet
2. Treat the indoor environment, especially where pets spend time resting
3. Treat the outdoor environment when necessary
4. Only use EPA-registered products that are labeled for these uses.

STORAGE and DISPOSAL: Collar should be left in place once fitted on cat. If collar is temporarily removed, do not set it on wood or other surfaces. **Storage:** Store in original unopened package away from children. **Disposal:** Do not reuse container or collar. Dispose of in trash. If collar is temporarily removed, wrap in paper or plastic; do not allow children to have access to collar.

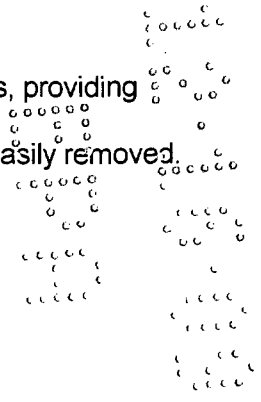
WHAT TO EXPECT:

For Fleas:

1. This [brand name] collar is designed to kill adult fleas and flea eggs.
2. Protection against fleas and flea eggs [hatch] will be achieved within a few days [48 hours], providing continuous protection for up to [35 weeks][245 days][8 months].
3. Replace collar every [35 weeks][245 days][8 months] or sooner if needed.

For Ticks:

1. Protection against adult and immature ticks will be achieved within a few days, providing continuous protection for up to [25 weeks][175 days][6 months].
2. Adult ticks will be killed over the entire pet. Dead ticks will fall off or may be easily removed.
3. Replace collar every [25 weeks][175 days][6 months] or sooner if needed.



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. **NOTICE: This product contains propoxur, a chemical known to the State of California to cause cancer. (in red bold).**

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 cats. Do not use on kittens under 12 weeks of age. Do not use this product on cats simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting** drugs or pesticides (eg. carbaryl or propoxur 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 cat with mild soap and rinse with large amounts of water.

FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
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 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 [1-800-XXX-XXXX] 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.	

To the extent consistent with applicable law, 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
1501 East Woodfield Road 200W
Schaumburg, IL 60173

100% satisfaction guaranteed or your money back. For product use information, call [1-800-XXX-XXXX] or visit our website [[zodiacpet.com][adamsfleacontrol.com][vet-kem.com][sergeants.com].

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

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

Made in USA

