



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-491	2. EPA Product Manager Stephanie Nguyen	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF 9907 Flea Collar for Cats & Kittens	PM # Registration Division	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1100 East Woodfiel Road, Suite 500 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

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION SEP 19 2002
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application	
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and section II.)
Amendment to revise Storage and Disposal (PRN 2001-6)

Section - III

1. Material This Product Will be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" 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 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. 0.2 - 1.5 oz.	No. per container 1	If *Yes Unit Packaging wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.2 - 1.5 oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other printed 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 Regulatory Specialist	Telephone No. (Include Area Code) (847) 330-5376
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.		6. Date Application Received (Stamped)
2. Signature <i>Nancy Huebl</i>	3. Title Regulatory Specialist	
4. Typed Name Nancy Huebl	5. Date 10-Sep-02	

2/17

[] indicates optional statements

RF-9907 FLEA COLLAR FOR CATS & KITTENS

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

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

Kills [Adult] Fleas [Fast] & Ticks [(including those carrying Lyme disease)]

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

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

PRECOR [vIGRen®] is Prevention

Long Lasting Protection

Ring of Prevention [Protection] against flea build-up in your home

PRECOR [vIGRen] breaks the flea life cycle

Works From Head to Tail

Quick [Fast] acting [action] [killing] for Fleas

Satisfaction 100% Guaranteed

Temporary wetting will not reduce effectiveness

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

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

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]

Kills [deer] ticks (including *Ixodes scapularis*), [up to 6 months][including those carrying Lyme disease] which may transmit Lyme disease [*borreliosis*]

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

Controls [Kills] Lyme disease [*borreliosis*]-carrying ticks

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

Flea protection for 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. _____

NOTIFICATION

SEP 19 2002

5/17

**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. Replace in [245 days][35 weeks][8 months] for continuous protection from adult fleas and flea egg hatch. Replace in [175 days][25 weeks][6 months] for continuous protection from ticks. [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

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 reuse collar. Dispose of in trash.

WHAT TO EXPECT:

For Fleas:

1. This [brand name] collar is designed to kill adult fleas and flea eggs.
2. This collar begins working to kill fleas and flea eggs as soon as it is placed around the cat's neck.
3. Protection against fleas and flea eggs [hatch] will be achieved within a few days [48 hours], providing continuous protection for [35 weeks][245 days][8 months].
4. Replace collar every [35 weeks][245 days][8 months] to help control adult flea infestations on your pet.

For Ticks:

1. Ticks are tougher to kill than fleas and are killed more slowly.
2. Full protection against adult and immature ticks will be achieved within a few days, providing continuous protection for [25 weeks][175 days][up to 6 months].
3. Adult ticks will be killed over the entire pet. Dead ticks will fall off or may be easily removed.
4. Replace collar every [25 weeks][175 days][6 months] for continuous protection from ticks.

4/7

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 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	
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. • [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, if present, after the first 5 minutes, then continue rinsing eye. • [Call a poison control center or doctor for treatment advice.]
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: *Atropine is antidotal only if symptoms of cholinesterase inhibition are present.	

5/17

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, IL 60173

100% satisfaction guaranteed. For product use information, call [1-800-XXX-XXXX] or visit our website [internet address].

**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

Wellmark

September 10, 2002

Document Processing Desk (AMEND)
Office of Pesticide Programs 7504C
U.S. Environmental Protection Agency
Room 266A Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

ATTENTION: Stephanie Nguyen, Registration Division

SUBJECT: LABEL AMENDMENT FOR STORAGE AND DISPOSAL/PRN 2001-6
FOR RF-9907 FLEA COLLAR FOR CATS & KITTENS/EPA REG. NO. 2724-491

Dear Ms. Nguyen:

Enclosed is a completed EPA Form 8570-1 and 5 copies of revised labeling for the above product. The Storage and Disposal is being revised based on PRN 2001-6 but the PR Notice does not provide text for pet collars. Therefore, I contacted Rame Cromwell of the Labeling Unit, and the text I've used was based on his guidance. For your convenience, I have also included 1 highlighted label to indicate where changes were made (red is added text, blue ~~strike through~~ is deleted text). Please expedite since there is an October 1, 2003 deadline for this change and we need to produce labels for production prior to October.

If you have any questions please, call me directly at 847-330-5376. Thank you for your assistance in this matter.

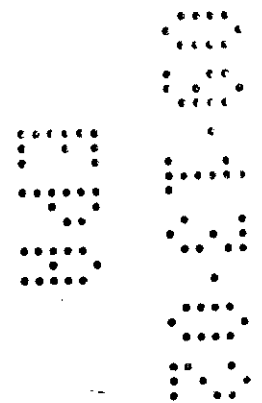
Yours sincerely,
WELLMARK INTERNATIONAL



Nancy Huebl
Regulatory Specialist
nancy.huebl@wellmarkint.com

enclosure

cc: G. Sandberg/C. Elmi/J. Richardson



7/7

Label Review Sheet

FILENAME: g:\LABELS\CAHSPEC\
02724491\amend S&D cat
collar 902 **COVERSHEET
UPDATE:** September 2002

PRODUCT: RF-9907 **EPA REG. NO.:** 2724-491

APPROVED Amendment submitted **SUPERSEDES:** 9/24/01
9/11/02

OVERVIEW: Amendment to revise Storage & Disposal per PRN 2001-6

Page #	Description of Major Changes
2	Storage and Disposal – revised per guidance from Rame Cromwell – Labeling Unit (PRN 2001-6 provides no guidance for pet collars – residential use)

