

2724-504

9-11-2006

1/8

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 4-20-03



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/2724-504

2. EPA Product Manager: George LaRocca

3. Proposed Classification: None Restricted

4. Company/Product (Name): Wellmark International/RF2004 (CCSO)

PM #: 13

5. Name and Address of Applicant / Registrant (Include ZIP Code):
Wellmark International
1501 East Woodfield Road, Suite 200W
Schaumburg, Illinois 60173

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 _____

Check if this is a new address

Section - II

Amendment - Explain below.

Resubmission in response to Agency letter dated _____

Notification - Explain below.

Final printed labels in response to Agency letter dated _____

"Me Too" Application

Other - Explain below.

NOTIFICATION

SEP 11 2006

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

Submission of optional alternate directions for use statement to reflect method of opening additional applicator style. 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 checked="" type="checkbox"/> Other (Specify) (foil)
* Certification must be submitted			

3. Location of Net Contents Information: Label Container

4. Size(s) Retail Container: 3-48 1 or 1.8 ml applicators

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

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

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
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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.

6. Date Application Received (Stamped)

2. Signature: Nancy Huebl

3. Title: Regulatory Specialist

4. Typed Name: Nancy Huebl

5. Date: August 29, 2006

2/8

[] Optional Copy

RF2004 (CCSO)

**Alternate brand names: ZODIAC® Spot On® Plus Flea & Tick Control for Cats 5 lbs. and Over
ZODIAC® Spot On® Plus Flea & Tick Control for Cats & Kittens Under 5 lbs.**

(General/Protection claims)

1 ml [cc] for cats under 5 lbs.; 1.8 ml [cc] for cats 5 lbs. and over

For use on cats [under 5 lbs.][5 lbs. and over]

Flea & Deer Tick [Protective] for cats [& kittens]

[Flea & deer tick] treatment for cats [& kittens]

[Special formula for cats/kittens][Superior flea prevention and treatment specially formulated for use on

[all] cats and kittens [12 weeks of age and older]

Spot On [Topical][Non-systemic] treatment for pets [cats]

Flea, Deer Tick, and Mosquito Treatment [Control][Prevention][Relief] for Cats & Kittens

4 in 1 Control [Protection][Treatment] (Fleas, Flea Eggs, Deer Ticks, and Mosquitoes)

[1 month][monthly][flea, deer tick, & flea egg][protection

Monthly treatment for [fleas, flea eggs, & deer ticks]

Flea [and deer tick][and mosquito] control for your pet

A smart approach to flea control

New and improved flea, deer tick, and mosquito control

Keeps fleas, deer ticks, and mosquitoes under control

[Advanced] Spot On [Plus] Insect Control [Treatment and Prevention]

A flea control program

Controls flea, deer tick, and mosquito problems

Pet-assured [secure] flea, deer tick, and mosquito protection

Provide your pet with flea, deer tick, and mosquito protection, right from the start

Provides protection

Direct on-animal protection from fleas, deer ticks, and mosquitoes

Provides relief [protection] from fleas, deer ticks, and mosquitoes

Once-a-month [topical][Spot On] protection from fleas, and deer ticks,

Long lasting, flea, deer tick, and mosquito protection

(Kills/Repels/Controls claims)

Kills [Controls] [adult] fleas, deer ticks, and flea eggs for [up to][4 weeks][1 month][per application]

Kills [and/or Repels] mosquitoes [for up to 18 days]

Controls fleas, deer ticks, and mosquitoes & prevents flea reinfestations [in your home]

Kills deer ticks (for up to 1 month [4 weeks]) [per application]

Kills deer ticks

(Disease claims)

Protects your pet [cat][kitten] from fleas, deer ticks, and mosquitoes (which may transmit heartworm disease)

Effectively controls fleas, deer ticks, and mosquitoes

Kills [Controls] deer ticks that may transmit [cause][Lyme disease][and Cytauzoonosis] for up to [1 month][4 weeks]

Protect your [cat] pet from [against] deer ticks that may transmit Lyme disease

Kills [and repels] mosquitoes that may transmit heartworm disease

Prevents mosquitoes from feeding on cats

Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation.

Preventative treatment for fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation

Protect your pet from insect pests [fleas, deer ticks, mosquitoes] that may transmit dangerous disease

Control highly-irritating flea, deer tick, and mosquito [insect] bites

(More general claims)

When it comes to fleas and deer ticks, there's no room for compromise
[Zodiac] protecting pets for over 35 years

(Flea egg/life cycle claims)

Kills [Controls] flea eggs for up to [30 days][1 month][4 weeks][per application]
Kills flea eggs, the source of home flea infestations and pet re-infestations, for up to [30 days][1 month][4 weeks]
Advanced [topical][flea egg treatment] that's easy and convenient to use
[Kills][Prevents][Keeps] flea eggs from hatching for up to [30 days][1 month][4 weeks]
Prevents flea eggs from developing into biting adults for up to [30 days][1 month][4 weeks][per application]
An effective flea topical [A Spot On] product that kills adult fleas and halts the development of flea eggs [immature stages in the flea life cycle]
Kills [flea] eggs before they hatch into biting adults
Prevents re-infestation for up to [1 month][30 days][4 weeks]
Kills hatching [developing] flea eggs
Interrupts normal flea development [Stops the flea life cycle]
Interrupts the flea life cycle
Breaks the flea life cycle for up to [1 month][4 weeks][30 days]
Controls[Kills][Lasts][Works][Protects] flea infestations for up to [1 month][4 weeks]
One-two punch controls fleas and flea eggs
Controls existing fleas and flea eggs, plus [and][prevents] future flea infestations

(Application claims)

[#] pack [# days'] [#] doses [1/2/3/4/5/6] months supply
One tube gives [1 month][4 weeks] of protection
[Pre-measured][Convenient][No mess][easy][simple] to [use][handle][apply] disposable applicator [tube]
Convenient [and effective], once-a-month [liquid][topical][Spot On] solution
Practical solution
Simple choice [flea & deer tick control]
A [One] simple application provides your pet with protection for up to [1 month]
Apply to one spot for head to tail (total body) flea protection [control]
Apply to 1 spot - spreads over the cat's [entire] body [from head to tail] through natural skin oils
Spreads naturally with cat's skin oils
[Plus] Contains a natural coat conditioner
[Once][One] Monthly Application
Easy to use [once] monthly application [liquid] prevents [and controls] fleas [& deer ticks]
Reapply [Repeat] [once] monthly
Repeat [treatment] every month
Monthly Control [Relief][treatment]

(Applicator claims)

Unique Applicator [tube] Shape [Design][helps prevents misuse on dogs][helps prevents misapplication on dogs]
Unique shape [for cats & kittens 5 lbs and over][for cats & kittens under 5 lbs]
Pet Specific® Applicator
Accu-Tip Dispenser
Easy to apply [identify][use] applicator [tube]
Cat head shape [applicator][tube] for cats [cat head = cats]
The right choice [applicator][tube] for the right pet
Make [Select] the right choice [applicator][tube][shape]

Choice [selection] is simple
 Easy choice
 Simple choice delivery system
 Easy to use applicator [tube] [provides direct on-animal protection]
 Longer Applicator [tube][tip] for easy application [to long-haired cats]
 Longer tube [applicator][tip] is ideal for long-haired pets [cats]
 Helps Prevent [misapplication on dogs] misuse on dogs with unique [specially designed] applicator [tube] design
 Cat head shape prevents misuse [misapplication][on dogs]
 Unique tube [applicator] design (pet shape) helps prevent misuse/misapplication [on dogs]
 EZ-squeeze [Easy squeeze] tube [applicator][shape]

(Product Claims)

Odorless
 Effective Control [Relief][Prevention]
 Fast [Quick] acting [Relief]
 Quick acting, long lasting [treatment]
 Long lasting and easy to use [apply]
 [Flea prevention] Helps stop itching and scratching [from flea bites]

(IGR claims)

From ZODIAC®, the originator of Insect Growth Regulator [IGR] technology
 [Plus][Contains][With] PRECOR® [vIGRen®], the first insect growth regulator for flea control
 Contains [Features] an Insect Growth Regulator (IGR) to inhibit the development of flea eggs
 Flea control for cats with [PRECOR®][vIGRen®] Insect Growth Regulator (IGR)
 [(S)-Methoprene] Insect Growth Regulator (IGR) interrupts the development of the flea life cycle at the egg stage
 [(S)-Methoprene] Insect Growth Regulator (IGR) prevents the development of flea eggs into adult fleas [inhibits the development of flea eggs into adult fleas]
 Controlling flea reproduction is the first step in controlling flea populations on your pet and in your home
 [(S)-Methoprene] Insect Growth Regulator (IGR) prevents flea reinfestation on your pet and in your home
 Flea treatment and preventative with an [insecticide] adulticide and Insect Growth Regulator (IGR)

(Zodiac claims)

We (Zodiac) put(s) your pet(s) first
 Zodiac...putting (your pet) pets first
 Right choice = best defense
 Perfect choice
 Zodiac – caring & committed
 Zodiac makes the choice simple
 [Satisfaction guaranteed][Money-back guarantee]

(Formula claims)

Etofenprox provides a novel [smart] approach to flea, deer tick, and mosquito control
 Advanced Formula [for cats & kittens]
 Features [Contains] an [insecticide] adulticide to kill [and/or][control] adult fleas [deer ticks, and mosquitoes]

5/8

(Prevention claims)

Preventing fleas and deer ticks from infesting your pet is much easier than treating an existing problem

Flea prevention has never been easier

An excellent preventative, offering protection against fleas

Prevents flea, deer tick, and mosquito infestations

Prevents flea recurrence

Control flea infestations by preventing them

Flea prevention is the best flea control strategy

Quick and sure flea, deer tick, and mosquito prevention

A quick and sure way to avert a flea problem is to [prevent it] use a preventative

It is far easier to prevent fleas than to control them

Flea control involves [requires] preventative measures [for your pet][and][for your home]

[New][Year-round][Flea Treatment][Preventative]

Use a flea preventative year-round (to prevent painful bites, itching and scratching, discomfort)

(FRONT OR BACK PANEL)

ACTIVE INGREDIENTS:

(S)-Methoprene (CAS # 65733-16-6)3.6%

Etofenprox (CAS # 80844-07-1)40.0%

OTHER INGREDIENTS:56.4%

Total100.0%

KEEP OUT OF REACH OF CHILDREN

See back panel for ingredients and additional Precautionary Statements

EPA Reg. No. 2724-504

EPA Est. No.

Net Contents:

6/8

**READ ENTIRE LABEL BEFORE USE
USE ONLY ON CATS OR KITTENS 12 WEEKS OF AGE AND OLDER**

[Specially formulated for cats [& kittens]][For use on cats only][Do not use on other animals]

INTRODUCTION:

[RF2004CCSO is a topically applied [long-lasting] product specifically formulated for cats and kittens with [containing] [it also contains] an insect growth regulator (IGR)[S-Methoprene][to prevent and control flea infestations][to kill fleas before they hatch][which prevents flea eggs from maturing into biting adults]. It [This product] also contains the highly effective flea, deer tick, and mosquito killing agent [Etofenprox][Brand Name], which kills biting adult fleas, deer ticks, and mosquitoes your cat may acquire from its surroundings. A single application of RF2004 (CCSO) will provide egg hatch inhibition for up to 30 days [1 month][4 weeks]. Each package contains enough product for xx monthly applications (xx days of protection [control]). RF2004 (CCSO) provides relief from flea infestations for up to 1 month [4 weeks] by killing adult fleas on your cat or kitten and flea eggs in your home. Adult fleas can live on your pet while producing vast numbers of eggs, which drop off your pet and develop in the surrounding environment. Normal insecticides will not kill the flea eggs, but RF2004 (CCSO) [is designed to] kill(s) adult fleas and flea eggs, breaking the flea life cycle and providing your cat relief from flea bites at the same time.

After application, your cat's natural skin oils [disperse] carry RF2004 (CCSO) over your cat's body for protection against biting adult fleas and the development of flea eggs. Once adult fleas are evident on your cat, there is likely an infestation of flea eggs and flea larvae in your home. To completely kill the existing flea population, you may need to treat your home and your pet's bedding (home sprays, foggers), as well as your yard (yard spray/outdoor fogger) with traditional flea products approved for use on pets, around the home, or in your yard. RF2004 (CCSO) can be used in conjunction with other ZODIAC [HARTZ®] premise products. As with all flea products, they are [RF2004 (CCSO) is] most effective when used as part of a total program aimed at reducing all stages of fleas in the cat's environment. ZODIAC [HARTZ] products [They] are designed to complement each other in an integrated program for flea, deer tick, and mosquito management. To assure proper treatment, we recommend use of ZODIAC [HARTZ] products as directed to treat all pets in the household, as well as the indoor and outdoor home environments.]

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

This product contains xx monthly dosages [one monthly dose], each (1 and 1.8 ml [cc]). Do not apply more than once every month.

USE ONLY ON CATS AND KITTENS 12 WEEKS OF AGE AND OLDER.

Do not get this product in your cat's eyes or mouth.

[1 ml [cc] dose for use on cats and kittens under 5 lbs.

1.8 ml [cc] dose for use on cats and kittens 5 lbs. and over (Same size applicators with different fill amounts)]

[Bend at perforation and tear off 1st month's applicator.] Hold [applicator] upright [and bend area of plastic at perforation, tear off and discard.] [Hold applicator upright] and snap tip back, away from face and body. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the [applicator] tube on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried. Repeat application once monthly.

7/8

ALTERNATE PACKAGING DIRECTIONS 1 (CAT-HEAD APPLICATOR)

[Bend at perforation and tear off 1st month's applicator.] Hold [applicator] upright and bend numbered area of plastic at perforation, tear off and discard. Hold applicator upright away from face and body and use scissors to cut secure seal applicator tip. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the [applicator] tube on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 2

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Hold bottom of tube with one hand. With other hand, snap cap off. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the [applicator] tube on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried. Repeat application once monthly.

STORAGE AND DISPOSAL: **Storage:** Store in a cool, dry place. Do not store unused applicators [tubes] separately from their packaging. **Container Disposal: If empty:** Do not reuse empty applicator [tube]. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS: Repeated exposure to etofenprox can cause skin irritation.

HAZARDS TO ANIMALS: For External Use on Cats Only. **Do not use on kittens less than 12 weeks old.** Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

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

In case of an emergency or for product use information, call [phone number] or visit our Web site: [URL]

Wellmark International
Schaumburg, IL 60173
Made in USA

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

Adding a Dose Reminder section to appear as follows on the back panel:

First Monthly Application: Month _____ Day _____ Year _____
Second Monthly Application: Month _____ Day _____ Year _____
Third Monthly Application: Month _____ Day _____ Year _____
[Fourth Monthly Application: Month _____ Day _____ Year _____]

Wellmark

August 29, 2006

Document Processing Desk (NOTIF)
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: G. LaRocca

SUBJECT: NOTIFICATION OF LABEL REVISION PER PRN 98-10
RF2004 (CCSO)/EPA REG. NO. 2724-504

Dear Mr. LaRocca:

Enclosed is a completed EPA Form 8570-1 and one copy of revised highlighted labeling (red is new text) for the above product. Per PRN 98-10, §II E, Changes in Packaging and Related Labeling Statements, the revision involves the addition of an optional statement in the Directions For Use, (to advise the user to snap off the molded plastic header piece). This is being submitted due to a different type of applicator being used by a subregistrant. All of the criteria for §II E are met. I have enclosed a self-addressed postcard for notification confirmation.

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

Nancy Huebl
Regulatory Specialist
nancy.huebl@central.com

enclosure

cc: C. Elmi/J. Flegeau
C. Purcell, Central Life Sciences