

2724-811

11-10-2011

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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

NOV 10 2011

Dr. James McFadden
Senior Regulatory Project Manager
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, IL 60173

Dear Dr. McFadden,

Subject: Label Amendment (R340)
Product Name: RF2164 A/T Combo
EPA Reg. No. 2724-811
Submission dated June 14, 2011

The labeling above, submitted in accordance with the Federal Insecticide, Rodenticide and Fungicide Act, as amended, is acceptable provided you:

1. Remove the statement : "Incidental exposure of cats to this product is not likely to cause harmful effects."
2. Remove the statement: "Based on testing, accidental exposure to cats from this product is not likely to cause harmful effects."

A stamped copy of the label and the Companion Animal Safety DER are enclosed for your records. Submit 2 copies of final printed labeling no later than 60 days from the date of this letter. Please contact Kevin Sweeney at (703) 305-5063 if you have questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

Richard Gebken
Product Manager
Insecticide Branch
Registration Division (7505P)

Enclosure

RF2164 A/T COMBO

[Text for "Dog" must be same size as Brand Name]

Front Panel - For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56 -80 lbs.), and Extra Large (81 lbs. and over) Dogs/Puppies 10 Weeks of age or older

Front Panel - For Use Only on Dogs/Puppies 10 Weeks of age or older

[Flea & Tick [& Mosquito][Treatment] [and] Control]

Spot-On Flea & Tick Control for Dogs & Puppies 10 Weeks of age or older

General Claims: (Note that claims previously approved for RF2042 CDSO, 2724-796, are in black text)

5 size categories provide [smaller] weight ranges to improve [maintain][deliver] efficacy

[performance][flea and tick][control][protection] on [for] your dog/puppy

Effective on indoor and outdoor dogs/puppies

[(1)[3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Spreads naturally with dog's/puppy's movement (skin and hair oils)

[Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Fresh][Clean][[Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

[Patent Pending]

[Incidental exposure of cats to this product is not likely to cause harmful effects]

[Can be used in households with dogs and cats]

[Based on testing, accidental exposure to cats from this product is not likely to cause serious harmful effects.]

Efficacy Claims:

Each tube [cartridge][vial] [application] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Controls fleas, ticks and mosquitoes for up to one month] [Monthly treatment for control of fleas, ticks and mosquitoes]

[Aids in Control of Ticks for up to 30 days]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (the major carrier of canine heartworm)

Monthly application for most effective protection

IGR Claims:

[Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [more than 10 weeks] up to [75 days][2.5 months]]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

**ACCEPTED
with COMMENTS
In EPA Letter Dated
NOV 10 2011**

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.**

2724-811

Applicator Claims

[New] [applicator]
 [New] contemporary design
 [brand name] [Applicator] helps to prevent getting liquid on [your] hands
 [brand name] [Applicator] tip parts hair to help [liquid][application] get down to [the][your][dog's/puppy's] skin
 Ergonomically contoured [ergonomic][shape][design] for easy handling [ease of use] [easy use]
 For use with [only][brand name][disposable][liquid dispensing] tubes [pods] [vials] [cartridges]
 [brand name] [applicator][has][provides][allows for][delivers] better grip
 [brand name][provides] re-closable [re-sealable] packaging for [easy] storage
 Closing [the][brand name][applicator] door automatically opens the [disposable][liquid dispensing] tube
 [pod][vial][cartridge]
 [brand name] [Applicator] [will not drip after opening]
 [brand name] [Applicator] Won't drip when set down as you go fetch the [your] dog/puppy
 Includes unique [brand] applicator
 Puts the liquid on your dog/puppy – not your hands
 Directs the liquid onto your dog[/puppy] – not your hands
 Directs the liquid onto your dog[/puppy] – away from your hands
 Applies liquid to your dog's[/puppy's] skin – not yours
 Helps prevent applying the wrong spot-on [dose] [product] on [to] the wrong pet
 Convenient, easy to use ACCU-TIP [Applicator] [DISPENSER]
 [Easy to use] Longer applicator tip for easy application to long-haired dogs/puppys

Thermoform claims

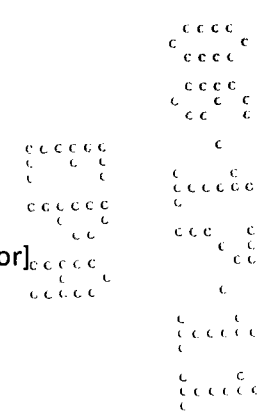
New
 New [disposable][liquid dispensing] tube [cartridge][vial][pod]
 (Note tube/vial/cartridge/pod used interchangeably)
 [New] [brand name][disposable][liquid dispensing] [tube][vial][pod] tip [helps][to] spread out liquid [on your][dog/puppy]
 Unique [cartridge] [tube][vial][pod] with flow control
 [no drip][no mess][application][tube][cartridge][vial][pod]

Promotional Package Copy

One month [dose] free
 One free month supply [dose] included
 Bonus pack
 Free [applicator][tube][vial][cartridge][pod]][inside]
 Designed not to drip when set on top of the counter, or table, or other flat surface.
 For use with [brand] applicator
 Applicator [device] not included
 [brand] Refill Pack [brand][applicator [device] not included]

Refill Claims

For use [only] with [brand name][Applicator]
 ([1][3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses
 Easy to use [convenient] refills
 [brand name (e.g., Adams or Bio Spot)] [brand name (e.g., Smart Shield)] [applicator]
 [tube][cartridge][vial][pod]refill pack [refills]
 Refill pack
 New [refill][tube][cartridge][vial][pod] design



Applicator name options (applicator device is used in text)

- Applicator
- Tool
- Device
- Applicator Device
- Application Tool

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Thermoform name options (tube, cartridge and vial are used in the text)

- Ampoule
- Cartridge
- Packet
- Pod
- Refill
- Tube
- Vial

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1).....	30.0%
S-Methoprene (CAS # 65733-16-6).....	3.6%
Piperonyl Butoxide (CAS # 51-03-6)*	5.0%
OTHER INGREDIENTS:	61.4%
TOTAL	100.0%

*(butyl carbityl) (6-propylpiperonyl ether) and related compounds

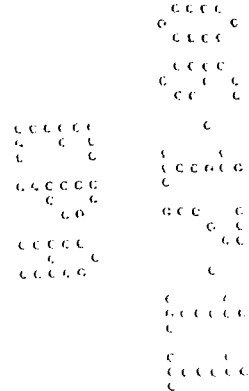
**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: One: 0.05 fl oz (1.5 cc) [vial][tube][cartridge] (Toy Dogs)/[and Puppies]
 0.10 fl oz (3.0 cc) [vial] [tube][cartridge] (Small Dogs)/[and Puppies]
 0.15 fl oz (4.5 cc) [vial][tube][cartridge] (Medium Dogs)/[and Puppies]
 0.20 fl oz (6.0 cc) [vial][tube][cartridge] (Large Dogs)/[and Puppies]
 0.30 fl oz (9.0 cc) [vial][tube][cartridge] (Extra Large Dogs)/[and Puppies]

EPA Reg. No. 2724-811
EPA Est. No.

[ICON – DO NOT USE ON CATS]



RF2164 A/T COMBO

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**IMPORTANT! DO NOT Use on Dogs LESS THAN 10 Weeks OLD
READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES. DO NOT USE ON OTHER ANIMALS!**

[Back Panel]

DO NOT USE ON CATS

Keep cats away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately.

[RF2164 A/T COMBO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2164 A/T COMBO also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

Effective flea & tick control for your dog/puppy.

[brand] provides flea and tick protection for dogs/puppies for up to 30-days – and protection from flea reinfestation beyond. That’s because it doesn’t just kill adult fleas and ticks, it also prevents reinfestation by knocking out flea eggs and larvae that could hatch later on. Plus, it kills and repels mosquitoes.

A unique, convenient applicator for you...

The new [brand] Applicator is specially designed to make applying flea and tick control easier, more precise -- and neater – than ever before. You simply insert the appropriate [brand] tube [vial][cartridge] for your dog/puppy into the applicator, close it and squeeze to apply. The applicator’s ergonomic, contoured shape [design] makes it easy to grip and a built-in fin [tip] [comb] helps to spread [part] the [your] dog’s/puppy’s hair to allow the liquid to more readily [better] reach [apply] the [to] [your dog’s/puppy’s] skin. The tube [vial][cartridge] is sealed inside, so you can be confident that the liquid goes onto your dog[/puppy] – and not your hand. Plus, if the applicator is laid down on a table, counter or other flat surface, it won’t run out or drip.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label.

USE RESTRICTIONS:

Apply this product once every 30 days unless a retreatment is necessary. Do not make the retreatment sooner than 8 days after the initial treatment. Do not retreat more than once per month.

RF2164 A/T COMBO works by application directly to the dog’s[/puppy’s] skin, not to the hair. When applying, use applicator device tip to push aside dog’s[/puppy’s] hair to allow direct application to the skin. Do not get this product in dog’s[/puppy’s] eyes or mouth. [(Note: Application now assumes one tube[vial][cartridge] per dog[/puppy] per application)]

The RF2164 A/T COMBO provides a unique applicator device that allows dog/puppy owners to treat their dogs/puppies more securely, and dispose of liquid cartridges [tubes][vials] with less mess.

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[Note: Each package contains sufficient cartridges/tubes/vials for [X] applications]

[DFU Set No. 1]

FOR [TOY][SMALL][MEDIUM] SIZE DOGS/PUPPIES

To apply the [RF2164 A/T COMBO] treatment, use one disposable liquid cartridge [tube][vial][for each application] with the applicator device.

1. OPEN [icon]

Use finger scoop to lift open [color, e.g. green] door.

2. LOAD [icon] (2 alternate statements)

-[To Load, place tube [cartridge][vial] white side up into open applicator with front of tube placed under tab on door.

-[To Load, place tube [cartridge][vial] white side up into the[open] applicator with tip end of tube placed under the [color][U-shaped] tab on door]

[Ensure that tube [cartridge][vial] fits securely in the applicator.]

3. CLOSE [icon]

Gently close the [color, e.g. green] door [and] the tube will snap open.

4. APPLY [icon]

The dog/puppy should be standing for easy application. To apply, use [front edge of applicator][tip] to part hair and get next to dog's/puppy's skin. Press [circle] [[round] thumb pad] on [color –green] door [number –once] at each of [two] (Toy Dogs/Puppies) [three] (Small Dogs/Puppies) (Medium Dogs/Puppies) evenly placed spots between the shoulder and the base of the tail.

Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy. Do not spread RF2164 A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after treatment will help to distribute the material over the skin.

5. DISPOSE [icon]

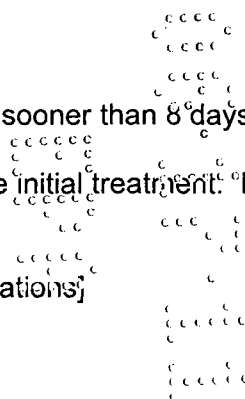
[When finished, hold applicator device over trash.] To dispose of empty tube, open [color, e.g. green] door and drop empty tube into trash or offer for recycling if available. [Close applicator device door and store in original package.]

6. USE RESTRICTIONS: (2 alt. statements)

- Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.

- If necessary, product can be reapplied, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.

[Note: Each package contains sufficient cartridges/tubes/vials for [X] applications]



FOR [LARGE][EXTRA LARGE] DOGS/PUPPIES

2
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- 1
- 2
- 3
- 4
- 5
- 6

APPLY [icon]

The dog/puppy should be standing for easy application. To apply, use [front edge of applicator][tip] to part hair and get next to dog's/puppy's skin. Press [circle] [[round] thumb pad] on green door [number-once] at each of four or five evenly placed spots between the shoulder to the base of the tail. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy. Do not spread RF2164 A/T COMBO by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after treatment will help to distribute the material over the skin.

[Note: Each package contains sufficient cartridges/tubes/vials for [X] applications]

RF2164 A/T COMBO is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with RF2164 A/T COMBO rapidly kills fleas and may reduce the incidence of this condition.] [RF2164 A/T COMBO is water resistant and remains efficacious following exposure to rainfall or swimming.]

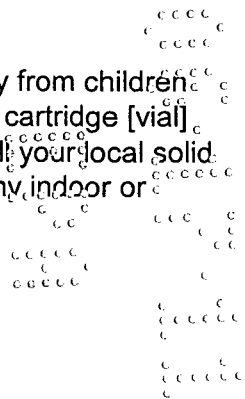
TREATMENT SCHEDULE			
Dosage: 1 [cartridge] [tube][vial] every 30 days per dog/[puppy]			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2164 A/T COMBO from: _____

NOTES: _____

Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **Pesticide Storage:** Store in a cool area away from children and animals. Liquid Cartridge [vial][tube] **Disposal: If empty:** Do not reuse cartridge [vial] [tube]. Place in trash or offer for recycling if available. **If partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.



**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION**

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DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Some dogs may experience hair loss or temporary skin irritation at the application site. If signs persist or become more severe, contact veterinarian immediately and report incident to company at 1-800-XXX-XXXX.

FIRST AID	
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 first 5 minutes, then continue rinsing• Call a poison control center or doctor for treatment advice.
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.	

WARRANTY AND CONDITIONS OF SALE:

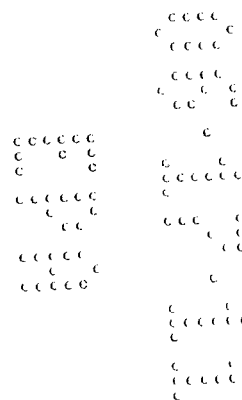
Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness 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.

In case of emergency or for product information, call 1-800-xxx-xxxx or contact your veterinarian if your pet is experiencing an adverse event.

Wellmark International
1501 E. Woodfield Road. 200W
Schaumburg, Illinois 60173

[URL]

Made in USA



TEXT FOR LIQUID TUBE/CARTRIDGE/VIAL

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Product name
Etofenprox 30%, (S)-Methoprene 3.6%, Piperonyl Butoxide 5%
KEEP OUT OF REACH OF CHILDREN
CAUTION
READ DIRECTIONS BEFORE USING
EPA Reg. No. 2724-811
Net Contents

[ICON – DO NOT USE ON CATS]
For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56 -80 lbs.), and Extra Large (81 lbs. and over) Dogs 6 months of age or older

[SUB-LABEL FOR REFILL CARTRIDGES]

[Product Name]
[Flea & Tick [& Mosquito][Treatment] [and] Control]
Spot-On Flea & Tick Control for Dogs/Puppies

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1).....	30.0%
S-Methoprene (CAS # 65733-16-6).....	3.6%
Piperonyl Butoxide (CAS # 51-03-6)*	5.0%
OTHER INGREDIENTS:	<u>61.4%</u>
TOTAL	100.0%

*(butyl carbityl) (6-propylpiperonyl ether) and related compounds

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

EPA Reg. No. 2724-811
EPA Est No.

[Note: full directions for use to be used if space allows]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label.

To apply the RF2164 A/T COMBO treatment, use one disposable liquid cartridge [tube][vial][for each application] with the applicator device.

Remove one refill tube [cartridge][vial] from the package and insert into opened [brand name] applicator device. Make application according to label directions supplied with the [brand name] applicator device. If you need directions for application, please call 1-800-XXX-XXXX.

(Precautionary and Storage/Disposal) text included)

Wellmark International
1501 East Woodfield Road 200W
Schaumburg, Illinois 60173

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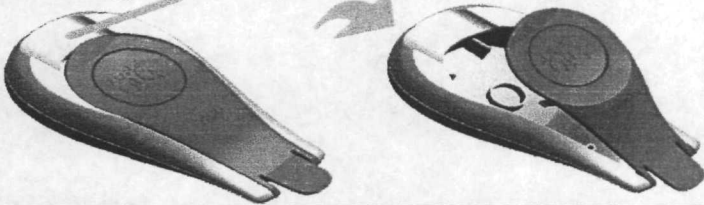
Icon Set for the RF2164 A/T COMBO
[ICON SET 1]

Directions for Use

For **Medium Dogs** (32 -55 lbs)

To apply the treatment, use applicator device with **ONLY ONE** liquid tube per application / per dog

Use finger scoop to lift **OPEN** green door



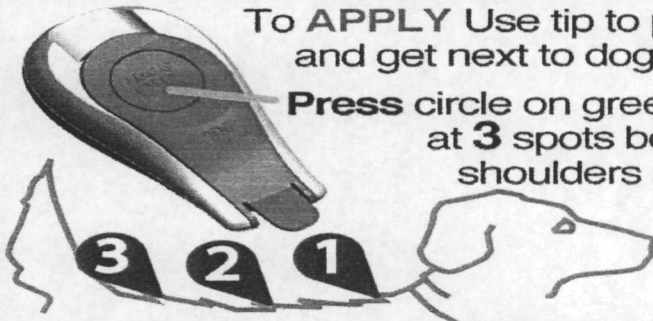
To **LOAD** place tube **WHITE** side **UP** into applicator with tip end of tube placed under tab on door



Gently **CLOSE** the door and the tube will snap open.

To **APPLY** Use tip to part fur and get next to dog's skin.

Press circle on green door at **3** spots between shoulders and tail



To **DISPOSE** of empty tube open green door and drop tube in trash



("#Spots" is a variable dependent on size of dog)