

83399-6

11-9-2007

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Joseph A. Conti
Sr. Regulatory & Development
Summit VetPharm LLC
400 Kelby Street
Fort Lee, New Jersey 07024

NOV 9 2007

RE: Additional marketing language for use on packages containing 18, 24 and 36
Ampules/pipettes, which will be sold to veterinarians for clinic/hospital use
EPA Reg. No.: 83399-6
Date of Submission: October 12, 2007

Dear Mr. Conti:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated October 12, 2007, for the product SVP7. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

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Print Form

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-



United States Environmental Protection Agency Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 83399-6	2. EPA Product Manager J. Hebert	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SVP7	PM# 1	
5. Name and Address of Applicant (Include ZIP Code) Summit VetPharm LLC 400 Kelby Street Fort Lee, New Jersey 07024 <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 type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION NOV - 9 2007
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

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

Additional marketing language for use on packages containing 18, 24 and 36 ampules/pipettes, which will be sold to veterinarians for clinic/hospital use. These include ; Clinic, Hospital, Vet, Puppy and Dog Pack.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> Text <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling 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 type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Joseph A. Conti	Title Sr. Director Regulatory & Development	Telephone No. (include Area Code)
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 statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Sr. Director Regulatory & Development	
4. Typed Name Joseph A. Conti	5. Date October 12, 2007	



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November 7, 2007

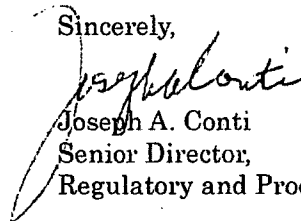
Ms. Joyce Edwards
U.S. Environmental Protection Agency
Office of Pesticides (7505P)
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: SVP 7 EPA Registration No. 83399-6

Dear Ms. Edwards,

In response to your e-mail concerning notification filed for the above product, Summit VetPharm certifies that the only additions to the label are those offered on the amendment.

Sincerely,


Joseph A. Conti
Senior Director,
Regulatory and Product Development

400 Kelby Street
Fort-Lee, NJ 07024
Tel: 800.999.0297
Fax: 201.585.9525

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NOTIFICATION

NOV - 9 2007

"Master Label"

(This master label includes label text for different size packages and application rates specific to the pet's age and body weight)

FRONT PANEL OF OUTER BOX

SVP7 (for Dogs and Puppies 2.5 to 20 lbs.)

SVP7 (for Dogs and Puppies 21 to 55 lbs.)

SVP7 (for Dogs 56 to 95 lbs.)

SVP7 (for Dogs over 95 lbs.)

Alternate Brand names;

Vectra 3D (for Dogs and Puppies 2.5 to 20 lbs.)

Vectra 3D (for Dogs and Puppies 21-55 lbs.)

Vectra 3D (for Dogs 56-95 lbs.)

Vectra 3D (for Dogs over 95 lbs.)

Vectra Gold (for Dogs and Puppies 2.5 to 20 lbs.)

Vectra Gold (for Dogs and Puppies 21-55 lbs.)

Vectra Gold (for Dogs 56-95 lbs.)

Vectra Gold (for Dogs over 95 lbs.)

Vectra Trio (for Dogs and Puppies 2.5 to 20 lbs.)

Vectra Trio (for Dogs and Puppies 21-55 lbs)

Vectra Trio (for Dogs 56-95 lbs)

Vectra Trio (for Dogs over 95 lbs)

(Optional marketing claims—front and side panels/continued on pages 6-9)

- For dogs and puppies over 7 weeks of age weighing 2.5 to 20 lbs. (1.6 ml)
- For dogs and puppies over 7 weeks of age weighing 21 to 55 lbs. (3.6 ml)
- For dogs weighing 56 to 95 lbs. (4.7 ml)
- For dogs weighing over 95 lbs. (8.0 ml)
- Effective monthly treatment of fleas, ticks, and mosquitoes
- Repels and kills fleas, ticks and mosquitoes for at least one month
- Prevents development of fleas, flea eggs, pupae and larvae for one month or more
- Kills 96% of fleas in 6 hours
- For dogs that enjoy the outdoors
- Remains effective after bathing and swimming
- Easy, spot-on (topical) application
- (Patented) applicator tip (Trademark) for easy application directly to the skin
- Guaranteed effective for at least one month
- New (first six months)
- New formula for your dog (first six months)

CCCCC
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- Performance guaranteed or your money back (SVP ICON) (Please call our professional staff at xxx-xxx-xxxx if you have any questions or comments about SVP7)
- SVP7 contains the insecticide dinotefuran, a neonicotinoid with knockdown effect. Permethrin is an effective insecticide/acaricide that complements dinotefuran in providing efficacy against fleas, ticks, lice and mosquitoes. Pyriproxyfen is an insect growth regulator which prevents development of all flea stages.
- Using the (patented) (Trademark) applicator, SVP7 is specially designed to spread naturally over the dog's body providing effective control of fleas, ticks, and mosquitoes for thirty days (four weeks, one month).
- New (first 6 months)
- New tick, mosquito and all stages of flea control (first 6 months)
- New formula for (your) dog(s) (first 6 months)

ACTIVE INGREDIENTS:

Dinotefuran	4.95%
Pyriproxyfen.....	0.44%
Permethrin	36.08%
OTHER INGREDIENTS.....	58.53%
TOTAL.....	100.00%

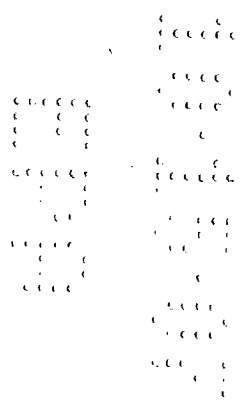
KEEP OUT OF REACH OF CHILDREN

WARNING: See package insert for (directions for use), (precautionary statements,) (first aid,) (and) (ingredients.)

**DO NOT USE ON CATS
[ICON OF CAT IN CIRCLE WITH SLASH THROUGH]**

BACK PANEL OF OUTER BOX

READ ENTIRE LABEL BEFORE EACH USE



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USE ONLY ON DOGS [OR] [AND] PUPPIES OVER THE AGE OF 7 WEEKS (OVER 7 WEEKS OLD) (7 WEEKS OF AGE OR OLDER)

DO NOT USE THIS PRODUCT ON CATS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

For external use on dogs only.

Do not use on puppies less than 7 weeks old.

WARNING: Causes eye irritation. Do not get in eyes. Harmful if swallowed. Harmful if absorbed through skin. Remove and wash contaminated clothing before reuse. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco products.

Do not use this product on debilitated, aged, medicated, pregnant or nursing animals or animals known to be sensitive to pesticide products without first consulting a veterinarian.

Sensitivity, such as slight transitory redness of the skin at the site of application, may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of individual animal sensitivity occur and persist, contact your veterinarian. Have the product container or label with you when calling your veterinarian for advice.

DO NOT USE ON CATS Due to their unique physiology and inability to metabolize certain compounds, this product must not be used on cats. If applied to a cat, or ingested by a cat that actively grooms a recently treated dog, this product may have serious harmful effects. If this occurs contact your veterinarian immediately.
(Cat icon)

FIRST AID	
If in eyes:	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. Call a poison control center or doctor for treatment advice
If swallowed:	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 a poison control

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	center or doctor. Do not give anything by mouth to an unconscious person.
If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center, doctor, or 1-800-222-1222 immediately 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 contact 1-800-222-1212 for emergency medical treatment information.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. [Precaución al consumidor: si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the User: If you cannot speak English, do not use this product until the label has been fully explained to you).]

HOW TO APPLY:

1. **USE ONLY ON DOGS. Do not use on cats or other animals.**
2. Remove applicator from package.
3. The dog should be standing or in a comfortable position for easy application.
4. **Unscrew the tube cap. Remove the cap from the tube. The cap contains a point that can pierce the safety seal on the tube. Carefully hold the tube upright, pointed away from your face and body. Using the cap puncture the safety seal on the tube. (Screw the applicator tip onto tube.)**

Alternate language--step 4, based on applicator:

Holding the applicator upright at the top below applicator tip, with thumb and index finger(of the other hand) (squeeze the tabs and) press down firmly to puncture safety seal locking the applicator tip in the dispensing position.

OR

Holding the applicator upright, place your thumb and index finger firmly around the collar. While maintaining applicator in an upright position, push firmly down on the top of the applicator tip, piercing the seal. (see illustration)

OR

(Remove the tube and applicator from the package. Unscrew the tube cap and replace with applicator tip.) Holding the tube (applicator) upright, place thumb and index finger around the applicator tip under the large disk. With other hand, grasp the stem of applicator tip above smaller disk. Press down firmly on small disk until both disks meet, piercing the seal. (See illustration)

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GRAPHICS DEPICTING HOW TO OPEN PACKAGE/APPLICATOR

5. [For dogs weighing 20 lbs. and under] Using the tip of the applicator, part the hair between the shoulder blades and slowly apply the product (to one spot) (as shown below) onto the skin, squeezing the applicator (tube) until empty. Avoid superficial application to the animal's hair.

OR:

5. [For dogs weighing 21 to 55 lbs][For dogs weighing 56 to 95 lbs:] Using the tip of the applicator, part the hair down to the level of the skin and slowly apply the product evenly to three spots along the dog's back, beginning between the shoulder blades and continuing in the order shown in the diagram below, squeezing the applicator (tube) is empty. Avoid superficial application to the animal's hair.

OR:

5. [For dogs weighing over 95 lbs:] Using the tip of the applicator, part the hair down to the level of the skin and slowly apply the product evenly to four spots on the dog's back, beginning between the shoulder blades and continuing in the order shown in the diagram below, squeezing the applicator (tube) is empty. Avoid superficial application to the animal's hair.

[GRAPHICS DEPICTING TREATMENT OF ANIMAL]
Do not get the product in your dog's eyes or mouth

6. Unscrew applicator tip and place back in package. Replace applicator tip with original cap and place in trash. OR Discard empty applicator (tube) as outlined in the Storage and Disposal section.
7. Repeat every month, or as recommended by your veterinarian.
8. For optimum treatment, control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks, lice and mosquitoes, (all) year-round treatment is recommended.

STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage and disposal.
Storage; Store in a cool, dry place. Protect from freezing.

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Disposal **If empty**, do not reuse the container. Place in trash or offer for recycling if available. **If partially filled**, call your local solid waste agency for disposal instructions. **Never place unused products down any indoor or outdoor drain.**

NET CONTENTS: X applications (applicators), each (0.06, 0.12, 0.16, 0.3 fl. oz. (1.6, 3.6, 4.7, 8.0 mL) *Example: 3 applicator package [Total 0.18 0.36, 0.48, 0.9 fl. oz., 4.8, 10.8, 14.1, 24.0 mL]*

(Volume varies with size of animal for which package is intended and number of applicators per package. Product may be packaged in 1, 2, 3, 4, 6, 8, 9, 12, 24 or 36 applicators per package. Total volume will correspond to number of applicators)

EPA Reg. No. 83399-6
EPA Est. No.

[Made in the USA (by)] [Distributed by:]
[Summit VetPharm, LLC]
[Fort Lee, NJ 07024]

PACKAGE INSERT (full label text plus additional copy)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Seller warrants that the material conforms to the chemical parameters of the US EPA registration and the label. To the extent consistent with applicable law, seller makes no warranty, express or implied, other than indicated on the label. Buyer and user assume all risk of use and handling of this material when such use and handling are contrary to the label instructions. To the extent consistent with applicable law, any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

ALTERNATE MARKETING TEXT

- Protects for at least one month
- Performance guaranteed or Summit VetPharm will supply replacement product
- Quick onset of flea activity (kill) within **2** hours
- Persistent efficacy through 30 days
- Prevents re-infestation (of fleas/of ticks) for up to one month
- Kills newly emerged fleas before they lay eggs
- Monthly treatment is recommended for optimal control and prevention of fleas, ticks, lice and mosquitoes
- Once monthly application
- X applicators
- X monthly doses (applications) (treatments)
- Quick-drying, non-greasy and water-resistant
- Easy to apply spot-on application
- Convenient, easy to apply
- Fragrance (odor) free
- Convenient to use
- Water-resistant
- Quick drying
- Non-greasy
- Convenient (easy to apply) topical treatment
- Convenient (easy to apply) topical treatment [with (patented) applicator tip] that allows application down to the skin
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, swimming or exposure to sunlight

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- Convenient topical treatment for dogs who enjoy the outdoors
 - Formulated for dogs that love the outdoors
 - For dogs that enjoy the outdoors
 - The killing of fleas, ticks and mosquitoes is important in the prevention of disease transmission by these parasites
 - (Only) available from (licensed) veterinarians
 - Sold by veterinarians
 - Tested on puppies from 7 weeks of age
 - After application, SVP7 spreads naturally over the dog's body to provide (full body) (all-over) protection against fleas, ticks and mosquitoes
 - SVP7 provides ongoing protection against fleas, ticks and mosquitoes for at least one month (30 days)
 - Dinotefuran kills fleas within 6 hours
 - SVP7 also contains permethrin, an effective insecticide/acaricide that combines with dinotefuran to provide efficacy against fleas, ticks, and mosquitoes .
 - SVP7 contains the insect growth regulator pyriproxyfen that acts to prevent the development of all flea stages for at least one month (30 days).
 - Approximately 95% of the flea population in a household infestation are immature flea stages that live in the dog's environment.
 - Questions or comments—please call (tel. no.)
 - For more information call (tel. no.)
 - For emergencies call (tel. no)
-
- Kills the vectors that may cause Lyme disease, Rocky Mountain Spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis and heartworm disease
 - Kills fleas, ticks and mosquitoes before they lay eggs
 - Repels and kills fleas, ticks and mosquitoes
 - Effective monthly treatment of fleas, ticks and mosquitoes
 - Easy, fast, effective control of fleas, ticks and mosquitoes that lasts at least 1 month
 - Protects against [4 types (species) of] ticks(Rhipicephalus spp, Dermacentor variabilis, Ixodes scapularis, Amblyomma maculatum), [3 types (species) of] mosquitoes (Culex spp, Ochlerotatus spp, Aedes spp) and all stages of fleas
 - Kills over 95% of fleas in 6 hours and up to 100% in 12 hours
 - Kills fleas that may transmit disease, including bartonellosis and tapeworm disease
 - Kills fleas before they lay eggs
 - Kills and repels fleas before they lay eggs
 - Regular use protects against all stages of the flea life cycle
 - Kills fleas that may cause flea allergy dermatitis
 - The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with SVP7 rapidly kills fleas and may reduce the incidence of FAD.
 - SVP7 is useful for dogs susceptible to Flea Allergy Dermatitis (FAD)
 - Regular use (of SVP7) breaks the flea life cycle
 - Protects against all stages of the flea life cycle

- Prevents development of all flea stages for at least 1 month (30 days)
- Kills and repels ticks within 24 hours
- Repels and kills ticks that may (cause) (transmit) Lyme disease
- Repels and kills ticks including those that may transmit Lyme disease
- Repels and kills ticks that may transmit Lyme disease, Rocky Mountain Spotted fever, babesiosis, ehrlichiosis, hepatozoonosis
- Repels and kills Brown dog ticks (*Rhipicephalus spp*), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes scapularis*) and Gulf Coast ticks (*Amblyomma maculatum*)
- Repels and kills ticks including Deer ticks (vector of Lyme disease), American dog ticks (vector of Rocky Mountain Spotted fever), Brown dog ticks (vector of ehrlichiosis) and Gulf Coast ticks for at least one month
- Kills ticks that may carry and transmit the organism which causes Lyme disease
- Kills ticks that may carry and transmit babesiosis
- Kills ticks that may carry and transmit Ehrlichia
- Kills ticks [in 24-48 hours] before they can transmit Lyme disease
- Kills ticks[in 24-48 hours] before they can transmit Ehrlichia
- Repels ticks before they can attach to dogs and take a blood meal
- Repels and kills ticks, which may transmit disease
- Kills ticks before they can lay eggs
- Repels many ticks before they can attach and kills those ticks which attach to the dog
- Repels and kills mosquitoes (*Culex spp*, *Ochlerotatus spp*, *Aedes spp*) and vector for heartworm (*Dirofilaria immitis*) for at least one month
- Repels and kills up to 100% of mosquitoes for at least one month
- Proven treatment technology for flea infestations
- Proven treatment technology for the control of fleas, ticks and mosquitoes
- Recommended for use in an integrated flea management system
- Veterinarians [and the Companion Animal Parasite Council (CAPC)] (often) recommend year round use depending on the needs of your pet
- Veterinarians recommend year round use of an ectoparasite, such as SVP7
- Pyriproxyfen arrests the development of immature flea stages
- Pyriproxyfen metabolically attacks fleas
- Hospital Pack (for use with 18, 24 and 36 package)
- Clinic Pack (for use with 18, 24 and 36 package)
- Vet Pack (for use with 18, 24 and 36 ml package)
- Puppy Pack (for use with 1.6 and 3.6 ml, 18, 24 and 36 package)
- Dog Pack (for use with 4.7 and 8.0 ml, 18, 24 and 36 package)

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APPLICATOR LABELING

SVP7(for Dogs and Puppies 2.5 to 20 lbs.)
SVP7(for Dogs and Puppies 21 to 55 lbs.)
SVP7(for Dogs 56 to 95 lbs.)
SVP7(for Dogs over 95 lbs.)

KEEP OUT OF REACH OF CHILDREN

WARNING
READ ENTIRE LABEL BEFORE USE

Dinotefuran4.95%
Pyriproxyfen.....0.44%
Permethrin.....36.08%

X fl. oz. (X mL)

DO NOT USE ON CATS [ICON]

EPA Reg. No. 83399-6
EPA Est. No. TBD

Lot # (designation will identify producing establishment)



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November 7, 2007

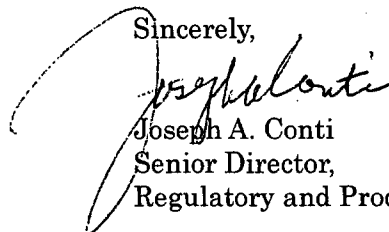
Ms. Joyce Edwards
U.S. Environmental Protection Agency
Office of Pesticides (7505P)
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: SVP 7 EPA Registration No. 83399-6

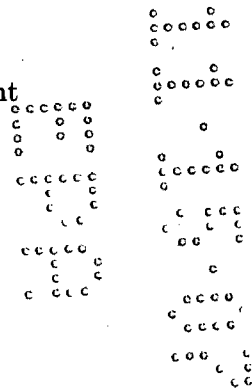
Dear Ms. Edwards,

In response to your e-mail concerning notification filed for the above product, Summit VetPharm certifies that the only additions to the label are those offered on the amendment.

Sincerely,



Joseph A. Conti
Senior Director,
Regulatory and Product Development



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Fort Lee, NJ 07024
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