

83399-4

12/19/2006

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DEC 19 2006

Mr. Joseph A. Conti
Summit Vetpharm, LLC
Parker Plaza
400 Kelby Street
Fort Lee, NJ 07024

Dear Mr. Conti:

Subject: Label amendment; additional efficacy claims
SVP4
EPA Registration Number 83399-4 (formerly 2596-155)
Your submissions dated 7/31/2006; 9/15/2006; 9/22/2006; and 12/13/2006

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7), is acceptable provided that you:

1. Submit and/or cite all data required for registration /reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Make the following label changes before you release the product for shipment:
 - a. Specify that this product is for use on cats and kittens 12 weeks or older. Provide a weight range of 3-5 lbs for the 1.2 ml size package, and 5-9 lbs for the 1.53 ml size package. Provide this weight range across the board, and clearly separate back panel text instructions for the two different size packages. You may follow the format of your last approved label dated 7/21/2006.
 - b. Delete all phrases referring to the product remaining effective even after bathing, swimming, water immersion or exposure to rain. This is not appropriate for a cat product.
 - c. Revise the claim "Works fast to kill the vector of bartonellosis (Cat Scratch fever)" to read "Kills fleas that may transmit disease, including bartonellosis."
 - d. Remove the parentheses from age and weight specifications on page one, and from

the optional marketing statements. These are mandatory restrictions, not optional statements.

- e. Add the following to the beginning of second ("Seller makes") and fourth ("Any damages....") sentences in the Limited Warranty and Limitation of Damages statement: "To the extent consistent with applicable law."
- f. Revise the Storage and Disposal statement as follows:
 - Do not contaminate water, food, or feed by storage and disposal.
 - Storage: Store in a cool, dry place. Protect from freezing.
 - Disposal: If empty, do not reuse the container. Place in trash or offer for recycling if available. If partially filled, call your local.....
- g. Remove all parentheses the referral statement on front panel, and separate this from the signal word. The signal word should be more prominent, and placed above the referral statement..
- h. Statements such as "Satisfaction guaranteed" or "Guaranteed effective for at least one month" need to be qualified (*e.g.*, or your money back), or must be removed from the label.
- i. Since you are marketing the product in two package sizes, reinstate the master label statement from the last accepted label dated 7/21/2006 on the front panel.
- j. Delete the statement, "wide margin of safety in mammals" and any other similar claims. Such safety claims are not permitted.
- k. Delete terms like "highly" effective, "excellent" efficacy, "works fast", "acts fast", "fast knockdown", "Fast", "Fast-acting", "long lasting", "the most resistant", "the most stubborn", "innovative", "specially formulated" and similar open ended heightened efficacy claims.
- l. Add the qualifier word "may" to all claims referring to "killing vectors or transmitter of", *e.g.*, "kills the vectors that may transmit....."
- m. Delete all references to flea allergy dermatitis. These disease prevention claims are not substantiated with submitted efficacy data.
- n. Delete the statement, "Fleas can cause secondary skin infections, transmit tapeworms, and cause anemia". This statement does not belong on this label.
- o. In the Hazards to Domestic Animals statement, delete reference to calling the company if signs of animal sensitivity occur. PR Notice 96-6 requires that a veterinarian should be called if signs of sensitivity occur. Use the following language: "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." Delete the sentence "If signs of individual animal sensitivity occur.....and persist"

- p. Delete the Questions and Answers section. This does not belong on a label, and cannot be considered a part of the EPA accepted labeling. However, this can accompany the product as a separate document (not part of the approved label). You must ensure the claims do not exceed those accepted on the label.
- q. Delete reference to the website. We have not seen what is on the website, and it cannot be considered a part of the labeling.
- r. Delete any reference to use of the product more than once in 30 days unless recommended by a veterinarian. This is an implied animal safety claim and cannot be allowed.

3. Submit two copies of the revised final printed label before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(a). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy the label is enclosed for your records. Copies of the companion animal study review, and efficacy reviews are also enclosed for your perusal. If you have any questions, please do not hesitate to contact me at (703) 308-8291, or send an e-mail.

Yours Sincerely,

Rita Kumar

Rita Kumar
Senior Regulatory Specialist
Insecticide-Rodenticide Branch
Registration Division (7505C)
e-mail: kumar.rita@epa.gov

Enclosures (4)

4/12

SVP5: EPA REG. NO. 83399-4
PROPOSED LABELING
Date: 12/13/06

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FRONT PANEL OF OUTER BOX

SVP5

Alternative Brand Name:

Vectra for Cats (over 5lbs)

Vectra for Kittens (4 to 6 months of age) or (under 5lbs.) (1.2 ml dose)

(Optional marketing claims—front and side panels/continued on pages 5-6)

- For cats & kittens over 12 weeks of age 1.2 ml size only
- Fast effective monthly treatment of fleas
- Protects from fleas for at least one month
- Kills fleas before they lay eggs
- Kills fleas within 6 hours
- Flea treatment specially formulated for cats (kittens 1.2 ml dose)
- Easy, spot on application
- Guaranteed effective for at least one month
- Kills fleas that may cause flea allergy dermatitis

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ACTIVE INGREDIENTS:

Dinotefuran.....14.85%

OTHER INGREDIENTS.....85.15%

TOTAL.....100.00%

KEEP OUT OF REACH OF CHILDREN

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

This version was also submitted on 11/15/06 to Jeanne Edwards for efficacy review.

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ACCEPTED
with COMMENTS
in EPA Letter Dated:
DEC 19 2006
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
As amended, for the pesticide
Registered under EPA Reg. No.
83399-4

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SVP5: EPA REG. NO. 83399-4
PROPOSED LABELING
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BACK PANEL OF OUTER BOX

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON CATS (KITTENS OVER 12 WEEKS OF AGE or under 5lbs. 1.2 ml dose)

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Causes moderate eye irritation. Avoid contact with 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, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on cats (kittens 1.2 ml dose).
For use on cats over 6 months old or over 5lbs.. (1.53 ml dose)
For use on kittens from 4 to 6 months old or under 5lbs.. (1.2 ml dose)

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OR

Do not use on kittens less than 12 weeks old (1.2 ml dose)
Do not use on cats less than 6 months old (1.53 ml dose).

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 (or call) [company] [at] [telephone number]. Have the product container or label with you when calling (company) (or) your veterinarian for advice.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

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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, doctor, or 1-800-222-1222 immediately for treatment advice
If swallowed:	Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. 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.

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. Remove one applicator tube from the package and hold in an upright position.
2. The cat (kitten 1.2 m dose) should be in a comfortable position for easy application.
3. 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 the face and body. Puncture the safety seal of the tube.

[Instruction for alternate package replaces step 3 above:

3. *Holding the applicator upright and with the end of the applicator tube pointing away from your face and body, push firmly down on applicator cap to puncture safety seal.] or [Holding the applicator upright with the end of the applicator tube pointing away from your face, grasp the tube in hand squeeze tabs and press down on applicator tip to perforate the safety seal.]*

[Instruction for alternate package replaces step 3 above:

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4. Holding the applicator upright, with thumb and middle finger squeeze the tabs, while pressing firmly down on applicator cap with index finger to puncture safety seal.]

GRAPHICS DEPICTING HOW TO OPEN PACKAGE/APPLICATOR

4. Part the hair down to the level of the skin and slowly apply the product at the base of the cat's kitten's 1.2 ml dose head until the applicator is completely empty, as shown in the diagram below. Avoid superficial application to the animal's hair.

[GRAPHICS DEPICTING TREATMENT OF ANIMAL]
Do not get the product in your cat's (or kitten's) eyes or mouth

5. Discard empty applicator as outlined in Storage and Disposal.

6. Repeat every month, or as needed. Do not reapply more frequently than every 30 days unless recommended by your veterinarian.

7. For optimum treatment, control and prevention of fleas, year-round treatment is recommended.

STORAGE AND DISPOSAL

Storage: Do not contaminate water, food or feed by storage and disposal. Store in a cool, dry place. Protect from freezing. 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 or 1-800-CLEANUP for disposal instructions. Never place unused products down any indoor or outdoor drain.

NET CONTENTS: X applications (applicators), each 0.052 fl. oz. (1.53 mL) [Total X fl. oz., X mL]

NET CONTENTS: X applications (applicators), each 0.041 fl. oz. (1.2 mL) [Total X fl. oz., X mL]

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SVP5: EPA REG. NO. 83399-4

PROPOSED LABELING

Date: 12/13/06

EPA Reg. No. 83399-4

EPA Est. No.

[Made in the USA (by)] [Distributed by:]

[Summit VetPharm, LLC]

[Fort Lee, NJ 07024]

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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. 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. 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 cat (kittens 1.2 ml dose) from fleas for at least one month
- Satisfaction guaranteed
- Fast acting
- Long-lasting
- Prevents (re-)infestation for at least one month
- Monthly treatment is recommended for optimal control and prevention of fleas
- Begins working upon application
- 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
- No noticeable odors
- Convenient to use
- Water-resistant
- Convenient (easy to apply) topical treatment
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Still works after bathing
- Still works after exposure to sunlight
- Still works after swimming
- Convenient topical treatment specially formulated for cats (kittens over 12 weeks of age 1.2 ml dose),
- Specially formulated for cats (kittens over 12 weeks of age 1.2 ml dose)

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- For cats and kittens over 12 weeks of age 1.2 ml dose)
- Fast kill of fleas is important in the prevention of disease transmission by (these) parasites
- Available from (licensed) veterinarians
- Sold by veterinarians
- Formulated for cats (kittens from 12 weeks of age 1.2 ml dose)
- After application, SVP5 spreads naturally over the cat's body to provide (full body) (all-over) protection against fleas
- After application, SVP5 spreads across the cat's body by the natural movement and grooming of the cat (kitten) to provide (full body) (all-over) protection against fleas
- SVP5, provides ongoing protection against fleas (and the diseases they may transmit) for at least one month
- Fast acting effective monthly control of adult fleas
- SVP5 contains dinotefuran, a neonicotinoid insecticide with a fast knockdown, which is highly specific to the nervous system of insects, and has a wide margin of safety in mammals.
- Dinotefuran kills fleas within 6 hours
- SVP5 kills fleas within 6 hours
- Questions or comments—please call (tel. no.) or email us at (email address)
- For more information call (tel. no.) or email us at (email address)
- For emergencies call (tel. no.)
- For more information visit our website www._____
- Works fast to kill the vector of bartonellosis (Cat Scratch fever)
- Kills fleas
- Fast, effective monthly treatment of fleas
- Easy, fast, effective control of fleas that lasts at least 1 month
- Kills over 95% of fleas in 6 hours and up to 100% in 12 hours
- Acts fast to kill fleas that may transmit disease, such as bartonellosis (including Cat Scratch fever)
- The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of cats and kittens over 12 weeks of age 1.2 dose) with SVP5 rapidly kills fleas and may reduce the incidence of this condition.
- Regular use breaks the flea life cycle
- Fleas can cause secondary skin infections, transmit tapeworms, and cause anemia

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- Begins working prior application and kills up to 99% of fleas within 6 hours
- Innovative proven treatment technology for the most resistant flea infestations

Proven treatment technology for the most stubborn flea infestations

NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

NEXT DOSE STICKERS AND REMINDER CALENDAR

It can be hard to remember when your cat's due for its next dose of Product. So we developed these tools to help you keep track of every dose. When you use the last tube in this package, call your veterinarian to order more Product.

Attach these stickers to your wall calendar or day planner on the date you give the first dose of Product, and then place another sticker on the same date for each of the next two months.

To use the calendar, simply write in the dates you are planning to use Product. Then, peel off the backing and place it in a hard-to-miss location.

Product Product Product

TIME FOR A REFILL



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NEXT DOSE STICKERS: AI

It can be hard to remember w of Vectra. So we developed the every dose. When you use the veterinarian to order more Vec

Attach these stickers to your's the date you give the first dos sticker on the same date for e



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SVP5: EPA REG. NO. 83399-4
PROPOSED LABELING
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APPLICATOR LABELING

SVP5

KEEP OUT OF REACH OF CHILDREN

CAUTION
READ ENTIRE LABEL BEFORE USE

Dinotefuran.....14.85%

0.052 fl. oz. (1.53 mL)
0.0441 fl. oz. (1.20ml)

EPA Reg. No. 83399-4
EPA Est. No. TBD

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Lot # (designation will identify producing establishment)

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