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WIRONMENTAL PROTECTION AGENCY	EPA Registration No	Date of Issuance			
Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave NW Washington D C 20460	88966-1	September 20 2012			
NOTICE OF PESTICIDE ☑ Registration	Term of Issuance Unconditional				
C Reregistration (under the Federal Insecticide Fungicide and Rodenticide Act, as amended)	Name of Pesticide Product VETGUARD FOR CATS				
Name and Address of Registrant (include ZIP Code) Tru Prodigy c/o Plyxis Regulatory Consulting, Inc 4110 136 <sup>th</sup> Street NW Gig Harbor, WA 98332 Note Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product - always refer to the above EPA registration number.					
har free a second stranger of the contract state and the second state of the second state of the second state s					
On the basis of information furnished by the registrant, the above named pest Insecticide Fungicide and Rodenticide Act	icide is hereby registered u	inder the Federal			
Registration is in no way to be construed as an endorsement or recommendation protect health and the environment, the Administrator on his motion may					
a pesticide in accordance with the Act The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others					
This action is taken under the authority of section 3(c)(5) of the Federal Insecticide Fungicide and Rodenticide Act, as amended Registration under this section does not eliminate the need for continual reassessment of pesticides EPA may require submission of data at any time to maintain the registration of your product					
Terms of Registration					
1 EPA has registered the product listed above provided that the following change is made to the label before you release the product for shipment					
a Revise the EPA Registration Number to read 'EPA Registration No 88966-1					
2 This registration is time-limited and expires two years from the date this product is first released for shipment You must provide the Agency with a projected "release for shipment date" in writing within 30					
days of the date of this Notice of Registration The Agency will calculate the expiration date based on the					
projected release for shipment date" until an actual release for shipment date is provided in writing Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i e					
no alternate formulations or minor formulation amendments will be submitted and/or approved for this product except to allow for alternate sources of any individual inert ingredient)					
product except to allow for alternate sources of any individual mert ingredienty					
Signature of Approving Official	Date				
Refer to Page 3	September 20 2012				
Richard J Gebken Product Manager (10) Registration Division Insecticide Branch					

## Page 2 of 3

- 4 You must submit the following data within the timeframe described below Within sixteen (16) months of the date on this Notice of Registration provide to the Agency acceptable data packages for Guideline Studies OPPTS 830 6320 (Corrosion Characteristics) and OPPTS 830 6317 (Storage Stability)
- 5 You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on August 1, 2012 The quarterly reports are due two months after the end of each quarter Please flag any Confidential Business Information CBI) as such Enhanced incident reporting should be submitted to the Product Manager Quarterly sales information should be submitted to the Registration Division Immediate Office (attn Kimberly Nesci)

The following is a list of information that must be included in the quarterly reports for each incident EPA Registration Number Product name (brand name) Lot# Where purchased internet store Veterinarian Active Ingredient(s) Weight range for product Date on which incident occurred (mm/dd/yyyy) State in which the incident occurred (standard 2 letter abbreviation) Registrant case # Species dog cat other (specify) Breed (as reported by pet owner) Age months or years Sex M F or neutered Weight pounds Primary Route of Exposure dermal oral other animal inhalation, other Body System neurological dermatological GI respiratory, ocular other Major signs noted Time to Onset (hours days) Treated by veterinarian yes or no First time product used yes or no Misuse use on incorrect species overdose too frequent dosing other (describe) Any known precondition EPA Severity Code death major moderate minor Outcome died, recovered, still treated unknown

- 6 Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details
  - a All minor dermal and ocular irritation reports
  - b Summary table for cats showing number of incidents of each severity code for each route of exposure Each incident should only be reported once If one incident has several routes of exposure the order should be ocular > oral > dermal In other words an incident with both oral and dermal exposure would be Page 3 of 3

reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure

c A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure

d Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e g multi-pet households)

e A summary table for s showing number of incidents for each severity code for these age ranges <3 months 3-6 months 6-9 months, 9-12 months 1 yr, 2 yr, 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 10 yr 11 yr 12 yr 13 yr, 14 yr 15 yr >15 yr

f A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label

g A summary table for cat weight showing number of incidents for each product weight range This table should show number of incidents in cats weighing less than that product weight range number of incidents in cats in lower half of weight range number of incidents in cats in upper half of weight range and cats weighing more than the product weight range

h Table showing number of incidents for each cat breed

1 Table showing number of incidents in cat for each clinical sign

- J Table showing number of incidents in cat for each organ system
- k Report aggregate incidents, but do not combine moderate and minor incidents

7 If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary EPA may take regulatory action 8 Tru Product must adequately address all of the mitigation actions identified in the Agency's *Generic Pet* 

Tru Prodigy must adequately address all of the mitigation actions identified in the Agency s Generic Pet Spot-On Mitigation Plan available at the following internet site <u>http://www.epa.gov/pesticides/health/spot\_on\_meetings.html</u>

You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA

Two copies of the finished labeling must be submitted prior to releasing the product for shipment If you fail to comply with all of the **Terms of Registration** stated above the registration will be subject to cancellation in accordance with FIFRA sec 6(e) and/or automatically expire Your release for shipment of the product constitutes your acceptance of these conditions

A copy of your label stamped Accepted with Comments' is enclosed for your records If you have any questions concerning this action, please contact Mr Richard J Gebken at (703) 305-6701 or gebken richard@epa gov

Sincerely

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Richard Gebken Product Manager 10 Insecticide Branch Registration Division (7505C)

Enclosure

[Note to reviewer optional text is placed in brackets]

[Package Insert, Text]

## **VETGUARD FOR CATS**

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT Fipronil INERT INGREDIENTS TOTAL

9 7% <u>90 3%</u> 100 0%

## KEEP OUT OF REACH OF CHILDREN

## CAUTION

[Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas ticks chewing lice mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills adult fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva nymph and adult) including brown dog ticks (*Rhipicephalus sanguineus*) American dog ticks (*Dermacentor variabilis*) ione star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease haemobartonellosis ehrlichiosis babesiosis and anaplasmosis]

[Kills Brown dog ticks American dog ticks Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

ACCEPTED With COMMENTS In EPA Letter Dated September 20, 2012 Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg No BB966-1 [Package Insert, Text]

## STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage and disposal

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## PESTICIDE STORAGE

Store unused product in original container only out of reach of children and animals

## CONTAINER DISPOSAL

Nonrefillable container Do not reuse or refill this container If empty Place in trash or offer for recycling if available

If partly filled Call your local solid waste agency for disposal instructions Never place unused product down any indoor or outdoor drain

## FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment

**IF SWALLOWED** Immediately call a poison control center or doctor 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 center or doctor. Do not give anything by mouth to an unconscious person

**IF IN EYES** Hold eye open and runse slowly and gently with water for 15-20 minutes Remove contact lenses if present after the first 5 minutes then continue runsing eye Call a poison control center or doctor for treatment advice

**IF ON SKIN OR CLOTHING** 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

## PRECAUTIONARY STATEMENTS

## HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### HAZARDS TO HUMANS

**CAUTION** Harmful if swallowed Causes moderate eye irritation. Avoid contact with skin eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating drinking or using tobacco

Have the product container label with you when calling a poison control center or doctor or going for treatment. You may also contact 1 888-314 8588 for emergency medical treatment information

#### HAZARDS TO DOMESTIC ANIMALS

For external use only on cats Do not use on kittens under 8 weeks of age Individual sensitivities while rare may occur after using **ANY** pesticide product Pets may experience some temporary irritation at the site of product application If signs persist or become more severe within a few days of application consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated debilitated or aged animals. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week). For Customer Service call 1-888-314-8588

Side Effects After applying VetGuard for Cats check your cat for side-effects such as redness from skin irritation scratching or other signs of discomfort. In some cases vomiting or diarrhea have been reported from grooming after treatment. If you observe these signs or symptoms in your treated cat contact your veterinarian. You may also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent

## [Package Insert, Text]

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veterinarians and pharmacists on staff 24 hours/7 days per week) For Customer Service call 1-888-314-8588

#### PHYSICAL OR CHEMICAL HAZARDS

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COMBUSTIBLE Do not use or store near heat or open flame

VetGuard for Cats is approved for use on all cats including breeding pregnant and lactating queens and on kittens that are older than 8 weeks

VetGuard for Cats keeps on working even after cats are shampooed rinsed with water or if cats are outdoors and exposed to the sun or rain

#### Frequency of Application

Monthly application of VetGuard for Cats controls flea tick and chewing lice infestations You can reapply VetGuard for Cats once every 30 days

Fleas VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas or if your cat is in situations where reinfestation may occur you may apply VetGuard for Cats every 30 days.

**Ticks** VetGuard for Cats kills ticks for at least one month Apply VetGuard for Cats every 30 days to control ticks (larva nymph and adult) that may transmit Lyme disease Rocky Mountain Spotted Fever ehrlichiosis babesiosis and anaplasmosis

**Chewing Lice** VetGuard for Cats kills chewing lice for at least one month Apply VetGuard for Cats every 30 days to control chewing lice

**Mosquitoes** Apply VetGuard for Cats every 30 days to kill mosquitoes Mosquitoes are killed within 24 hours for up to 7 days and within 48 hours for up to 28 days

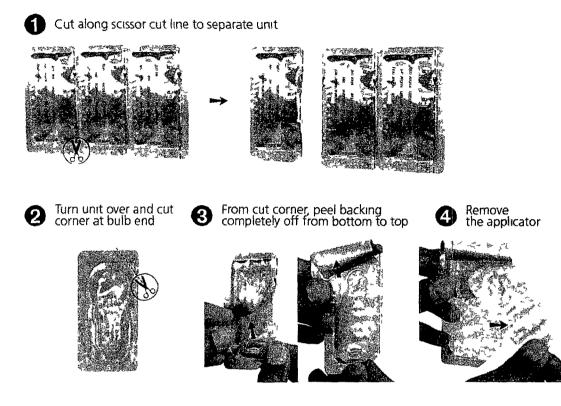
Use VetGuard for Cats on all cats including breeding pregnant and lactating queens and on kittens 8 weeks or older

A one-spot application is convenient and easy for effective treatment of fleas ticks chewing lice and mosquitoes Apply VetGuard for Cats when your cat is dry

VetGuard for Cat is applied at a single point on the surface of the skin between the cat's shoulders and rapidly covers the entire cat by localizing in the hair on the surface of the skin and in the sebaceous glands

Soon after coming into contact with a treated cat fleas ticks mosquitoes and chewing lice are killed. To kill fleas ticks chewing lice and mosquitoes apply VetGuard for Cats as follows

## Remove and Open Package



## **Open Applicator**

Hold upright with foil side away from you and snap applicator tip back to open

## Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair Place the open end of the applicator just above the skin and squeeze Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry



## LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT READ BEFORE USE Read the entire Directions for Use Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable return the unopened product container at once By using this product user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability

## [Package Insert, Text]

**CONDITIONS** The directions for use of this product are believed to be adequate and must be followed carefully However it is impossible to eliminate all risks associated with the use of this product ineffectiveness injury and other unintended consequences may result because of such factors as manner of use or application (including misuse) the presence of other materials weather conditions and other unknown factors all of which are beyond the control of Tru Prodigy All such risks shall be assumed by the user or buyer

**DISCLAIMER OF WARRANTIES** To the extent consistent with applicable law Tru Prodigy makes no other warranties express or implied of merchantability or of fitness for a particular purpose or otherwise that extend beyond statements on this label

LIMITATIONS OF LIABILITY To the extent consistent with applicable law neither Tru Prodigy the manufacturer nor the Seller shall be liable for any indirect special incidental or consequential damages resulting from the use handling application storage or disposal of this product. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses injuries or damages resulting from the use handling application or storage of this product whether in contract warranty tort negligence strict liability or otherwise shall not exceed the purchase price paid

EPA Reg No 88966-R

EPA Est No

#### Manufactured for

Tru Prodigy 500 E Shore Drive Suite 130 Eagle ID 83616

[Made in Germany]

[VetGuard for Cats is a registered trade name of Tru Prodigy]

[Optional Bar Code]

## [Carton Text - Front]

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# **VETGUARD FOR CATS**

For use ONLY on CATS & KITTENS 8 weeks and older

ACTIVE INGREDIENT Fipronil INERT INGREDIENTS TOTAL

9 7% <u>90 3%</u> 100 0%

Net Contents 0 21 fl oz (1 5 mL [3 tubes containing 0 017 fl oz each)

3 Doses

# KEEP OUT OF REACH OF CHILDREN

## CAUTION

See label insert for First Aid and Precautionary Statements

## [Optional marketing claims]

[Quick-acting]

[Long-lasting]

[Waterproof]

[For monthly control of fleas ticks chewing lice mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

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[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of ticks (larva nymph and adult) including brown dog ticks (*Rhipicephalus sanguineus*) American dog ticks (*Dermacentor variabilis*) lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease haemobartonellosis ehrlichiosis babesiosis and anaplasmosis]

[Kills Brown dog ticks American dog ticks Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Kills adult mosquitoes]

[Kills fleas ticks chewing lice and mosquitoes]





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Manufactured for

Tru Prodigy 500 E Shore Drive Suite 130 Eagle ID 83616

[VetGuard for Cats is a registered trade name of Tru Prodigy]

EPA Reg No 88966-R EPA Est No [Made in Germany] 10/15

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[Carton Text - Back]

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# **VETGUARD FOR CATS**

VetGuard for Cats can be used on all cats including breeding pregnant and lactating queens and on kittens that are older than 8 weeks. VetGuard for Cats controls fleas ticks chewing lice and mosquitoes and keeps on working even after cats are shampooed rinsed with water or if cats are outdoors and exposed to the sun or rain.

## DIRECTIONS FOR USE

It is a violation of law to use this product in a manner inconsistent with its labeling Do not allow children to apply product TO PREVENT HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY USE ON CATS ONLY DO NOT USE ON RABBITS OR ON OTHER ANIMALS

Side Effects See package insert for side effects

To kill fleas ticks chewing lice and mosquitoes apply VetGuard for Cats as follows

### **Remove and Open Package**

See package insert for opening instructions

### **Open Applicator**

Hold upright with foil side away from you and snap applicator tip back to open

## Apply VetGuard for Cats

Find a spot between the cat's shoulder blades and part hair Place the open end of the applicator just above the skin and squeeze Apply the entire contents of the applicator in a single spot directly onto the cat's skin. Avoid applying on top of the hair coat. Do not touch treated area until dry











VetGuard for Cats Draft Label - 9-19-2012 EPA File Symbol 88966-R

## [Carton Text - Back]

#### **Frequency of Application**

Monthly application of VetGuard for Cats controls flea tick and chewing lice infestations You can reapply VetGuard for Cats once every 30 days

Fleas VetGuard for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas or if your cat is in situations where reinfestation may occur you may apply VetGuard for Cats every 30 days.

Ticks VetGuard for Cats kills ticks for at least one month Apply VetGuard for Cats every 30 days to control ticks (larva nymph and adult) that may transmit Lyme disease Rocky Mountain Spotted Fever ehrlichiosis babesiosis and anaplasmosis

**Chewing Lice** VetGuard for Cats kills chewing lice for at least one month Apply VetGuard for Cats every 30 days to control chewing lice

Adult Mosquitoes Apply VetGuard for Cats every 30 days to kill mosquitoes Mosquitoes are killed within 24 hours for up to 7 days and within 48 hours for up to 28 days

Manufactured for Tru Prodigy 500 E Shore Drive Suite 130 Eagle ID 83616

EPA Reg No 88966-R

EPA Est No

[Made in Germany] [VetGuard for Cats is a registered trade name of Tru Prodigy]

#### [Carton Text - Front, Back, or Side Panel]

EPA Reg No 88966 R EPA Est No Batch/Lot No [Made in Germany]

## [Insert with Tips, Front Side, Text]

## [Optional marketing claims]

## VetGuard for Cats

See other side for stickers to remind you it s time to reapply VetGuard for Cats

Some Tips and Other Information for Using VetGuard for Cats

Treat dogs and cats separately and only with the proper dose of VetGuard for Dogs or VetGuard for Cats

Follow the label instructions for how to apply and be sure that VetGuard for Cats is applied to the skin not on top of the fur and not near the collar Removing the collar before application may help to prevent the collar from absorbing the VetGuard dose

Apply VetGuard for Cats when your cat is dry Make sure you apply all of the dose that is in the applicator

Even indoor cats need flea and tick control if other household pets bring fleas into the home

Fleas have many life stages and serious infestations can take up to 3 applications every 30 days for control In fact the flea life-cycle in the home can last as long as 21 days

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### [Insert with Tips, Back Side, Text with Stickers]

Calendar Reminder Stickers

Reminder It s time to repurchase VetGuard for Cats!

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You can use these stickers to remind you when to apply and to purchase VetGuard for Cats

The first time you treat your cat peel off the sticker and place on your calendar that day To remind you when the next application is due place the other two stickers on your calendar 1 and 2 months after the first application

3 Months Sticker 1 Apply VetGuard for Cats Sticker 2 Apply VetGuard for Cats Sticker 3 Apply VetGuard for Cats

For Customer Service call 1-888-314-8588 [For more information visit <u>www xxxxx com]</u>

Tru Prodigy

Tru Prodigy 500 E Shore Drive Suite 130 Eagle ID 83616



[Optional Bar code]



[Pictogram of Back of Blister With Opening Instructions]

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[Text for Back of Blister]

KEEP OUT OF REACH OF CHILDREN CAUTION See full label for additional instructions and precautions before using Only for Cats & Kittens VetGuard for Cats EPA Reg No 88966-R Lot/Batch No 0 017 fl oz (0 5 mL) 9 7% Fipronil 15/15