

70585-11

4/10/2014

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. P. Leanne Pruett
Novartis Animal Health U. S., Inc.
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

APR 10 2014

Subject: Label Amendment – Addition of General Marketing Claims and Label Edits

Product Name: EasySpot For Cats
EPA Registration Number: 70585-11
Submission Date: February 20, 2014
Decision Number: 488733

Dear Ms. Pruett:

The label amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is **acceptable**.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Products released for shipment after 18 months from the date on this notice or the next printing of the master label whichever occurs first, must bear the new revised label. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA. Amended labeling will supersede all previously accepted labels. Your release for shipment of this product constitutes acceptance of these conditions. As required by 40 CFR 156.10(6), you must submit one copy of the final printed label before the product is released for shipment. If you have any questions please contact Carlyn Petrella by phone at (703) 347-0439 or via email at "petrella.carlyn@epa.gov".

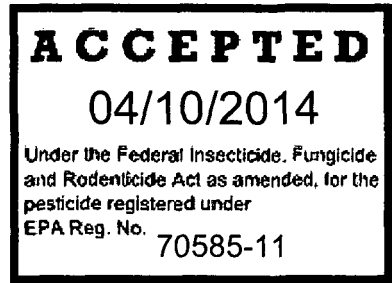
Sincerely,

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

Richard Gebken
Team Leader/Product Manager (10)
Insecticide Branch
Registration Division (7505P)
Office of Pesticide Programs

[Optional text appears in brackets -the final label may include some or all of the optional text on front, back, side, or inside label panels]

EasySpot™
For Cats
[(fipronil)]



[A][a]pply only to kittens more than 8 weeks old and over 1.5 lbs
[[alternate language] [A][a]pply only to kittens 8 weeks or older and over 1.5 lbs]

[Mosquitoes]

- [[Kills mosquitoes] [within 24 hours] [within 24 hours for up to the first 7 days after treatment, and within 48 hours for up to 28 days]]

[Adult Fleas]

- [Kills adult fleas [for up to six weeks] [!]]
- [Kills newly emerged adult fleas before they lay eggs]
- [Kills fleas, a source of flea allergy dermatitis] [, flea bite anemia]
- [If cat is a high risk for flea reinfestation, apply a once a month application]
- [Kills fleas [[for] up to [4 weeks] [1 month] [30 days] [!]]]

[Ticks]

- [Kills ticks, including those that may carry Lyme disease]
- [Kills ticks for up to [[4] [four] weeks] [1 month] [30 days]!]
- [Kills deer ticks [[that may carry Lyme disease,] for up to [[4] [four] weeks] [1 month] [30 days]]]
- [Kills ticks]
- [Kills brown dog ticks]
- [Kills ticks (including deer ticks) for up to [[4] [four] weeks] [1 month] [30 days]]]
- [Kills [brown], [American dog,] [and] [lone star,] ticks [(*Rhipicephalus sanguineus*)] for up to [4] [four] weeks] [1 month] [30 days]]]
- [Kills American dog ticks [(*Dermacentor variabilis*)] for up to [[4] [four] weeks] [1 month] [30 days]!]

[Multiple Infestations]

- [Kills chewing lice] [and] [[C][c]ontrols mites that may cause sarcoptic mange [infestations]]
- [Flea [&] [and] tick control only for cats [&] [and] kittens [8 weeks old and older] [more than 8 weeks old]]
- [Kills [fleas], [ticks], [chewing lice] [&] [and] [mosquitoes]]
- [Kills [fleas], [ticks], [mosquitoes] [and] [&] [chewing lice]]
- [Monthly [flea], [tick], [mosquito], and [chewing lice] [treatment]]
- [[Four] [Three] [4] [3] [-] way[s] [to kill] [control] [kills [fleas], [ticks], [mosquitoes] and [chewing lice]]
- [[4] [four] [-] week] [1 month] [30 day] [flea] and [tick] [&] [and] treatment]

- [[4] [four] [-] week] [1 month] [flea], [tick], [mosquito] and [chewing lice] control]
- [Once-a-month [flea] and [tick] treatment]
- [Use EasySpot™ [For Cats] monthly to control [fleas] [ticks] and [chewing lice]]
- [Monthly [flea], [tick], [mosquito] and [chewing lice].]
- [Kills [fleas] and [ticks] for up to [4] [four] weeks] [1 month] [30 days]!]
- EasySpot™ [For Cats] provides [convenient] and [effective] [flea], [tick] [,] [&] [and] [chewing lice] [and mosquito] control for cats and kittens 8 weeks and older.]

[All Others]

- [For use only on cats and kittens [more than 8 weeks old]]
- [For use only on cats and kittens [8 weeks old and older]]
- [Waterproof]
- [Fast-acting] [Fast acting]
- [Long-lasting] [Long lasting]
- [Prevents [flea] reinfestation]
- [Convenient spot treatment]
- [Once-a-month treatment]
- [A once monthly application for chewing lice]
- [Fast action against [chewing] lice infestations]
- [[One] [Two] [Three] [Four] [Five] [Six] [Twelve] [Twenty-Four] applications] and/or [[1] [2] [3] [4] [5] [6] [12] [24] -month supply] or [[4] [8] [12] [16] [20] [24] [48] [52] [104]-week supply] or [[1] [2] [3] [4] [5] [6] [12] [24] applications]
- [Best if used year round!]
- [4[-]week dose[!]] [in Child Resistant Packaging]
- [1[-]month dose[!]] [in Child Resistant Packaging]
- [30[-]day dose[!]] [in Child Resistant Packaging]
- [Easy-to-use [application]]
- [Specially formulated only for cats and kittens older than 8 weeks]
- [fipronil (9.7%)]
- [A fipronil product]
- [Contains fipronil[,] [-] the active ingredient in [Frontline Top Spot® for Cats*]]
- [*EasySpot™ [For Cats]] is not manufactured by or distributed by Merial. Frontline® Top Spot® is a registered trademark of Merial.]
- [Fast-acting, long-lasting that's also waterproof.]
- [[One][1][Two][2][Three][3][4][Four][5][Five][Six][6][Twelve][12][Twenty-Four][24]] [Easy to Use] Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][Four Month Supply][Five Month Supply][6 month Supply][12 Month Supply][24 month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply] [20 Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply] [in Child Resistant Packaging]
- [Cats can be bathed 24 hours after [application] [treatment] [EasySpot™ [For Cats]] is applied]]

- [Easy-to-use [application]]
- [[Free] calendar stickers inside!]
- [[Free] calendar stickers inside]
- [Apply once every [4 weeks] [month] [30 days]!]
- [Can be used on breeding, pregnant and lactating [cats] [queens] [female cats]]
- [[Free with purchase] [Free inside] [Monthly application reminder magnet]
- [clip] [insert] [inside]
- [Can be used only on kittens [more than 8 weeks of age]]
- [Can be used only on kittens [8 weeks of age and older]
- [Optional graphics: picture of all controlled pests with line through them]
- [Protection [P][p]ack]
- [Cats know what they want. You know what they need.]
- [This protection pack contains a single dose of EasySpot™ [For Cats], along with other valuable offers to help ensure that your cat is always protected.]

EPA Reg. No. 70585-11
 EPA Establishment No.

ACTIVE INGREDIENTS:

Fipronil 9.7 %

INERT INGREDIENTS: 90.3%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back][or][Side][or][Interior Panel][Label Panel[s] for Additional Precautionary Statements [and First Aid Statements].

NET CONTENTS:

[1][One][2][Two] [Three] [3] [Four][4][5][Five][6][Six][12][Twelve][24][Twenty-Four] [-]
 0.017 fl oz (0.50ml) applicators

[Back / Side Panel of Outer Packaging]

[EasySpot™ [For Cats]] contains fipronil to effectively kill fleas and ticks [[(]including those that may transmit Lyme disease)].

READ ENTIRE LABEL BEFORE EACH USE

[EasySpot™ [For Cats] provides [four-] [three-] way protection that kills [fleas], [ticks], [mosquitoes] and [chewing lice]. Kills deer ticks [that may transmit Lyme disease]. Kills brown dog ticks, American dog ticks and lone star ticks. Prevents flea reinfestation.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. 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 only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat your cat with more than one topically applied pesticide product at a time. Overdosing your cat can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated or aged cats. Can be used on breeding, pregnant, or lactating [cats][female cats][queens]. Consult a veterinarian before using on cats with known organ dysfunction.

FIRST AID	
If swallowed	Call a poison control center or a 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 center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes	Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on skin	Wash with plenty of soap and water. Get medical attention if irritation persists.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-637-0281.	

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 CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. Do not allow your cat to ingest this product. Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 1.5 lbs. Do not double-dose cats. Use entire contents of tube vial on each cat. [Do not split one tube between two cats.]

Side Effects

Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching, or other signs of discomfort. If signs of a sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or Novartis Animal Health at 1-800-637-0281. If

your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

[(INSERT DIAGRAM THAT DEPICTS APPLICATION OF PRODUCT ON THE CAT)]

How to Open: Remove product [tube[s]] [vial[s]] from the package. [Separate one tube from the others.] Hold the [tube] [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to apply: While holding the cat with one hand, use the other hand to apply the solution. Invert the [tube] [vial] and use the open end to part the cat's hair. Apply contents of one [tube] [vial] of EasySpot™ [For Cats] [as a spot between the shoulder blades] [as a stripe, starting high on the back of the cat's neck to in front of the shoulder blades]. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat. When finished, wrap the [tube] [vial] in paper and put into the trash. Only one applicator per treatment is needed. Repeat application may be made if necessary, but do not apply more often than once every 30 days.

[Optional drawings of application process that may or may not appear on finished label]

FREQUENCY OF APPLICATION

Use EasySpot™ [For Cats] monthly for control of [flea], [tick] [and] [chewing lice] [and mosquito] infestations. [Studies show that] EasySpot™ [For Cats] kills fleas for up to six weeks. If your cat is at high risk for flea reinfestation [or in a highly infested environment], apply monthly. Apply monthly to control [ticks], [mosquitoes] and [chewing] [lice]. [EasySpot™ [For Cats] kills mosquitoes within 24 hours for up to the first 7 days after treatment, then within 48 hours for up to 28 days.] EasySpot™ [For Cats] remains effective after water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. [Cats can be bathed 24 hours after treatment.] Do not reapply for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container.

If empty: Place in the 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.

[Outer Packaging or Interior Carton Panel]

WARRANTY

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of NOVARTIS ANIMAL HEALTH US, Inc. (NAHUS) or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold NAHUS and Seller harmless for any claims relating to such factors.

NAHUS warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or NAHUS, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NAHUS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with State law, in no event shall NAHUS or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF NAHUS AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF NAHUS OR SELLER, THE REPLACEMENT OF THE PRODUCT.

[If you have questions or comments about this product, please write to: Novartis Animal Health US, Inc., (address).]

For Technical Information call: 1-800-637-0281 [hours of service]
[Made in USA]

[Distributed by] [Manufactured for][Available exclusively from]:
Novartis Animal Health US, Inc.
3200 Northline Avenue, Suite 300
Greensboro NC 27408

[BAR CODE AREA]

EPA Reg. No. 70585-11
EPA Est. NO. XXXXX-XX-XXX

[Optional Exterior or Interior package copy]

[How to Apply - May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

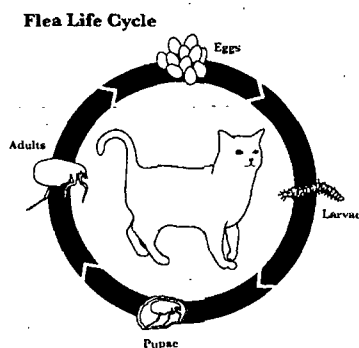
How to Open:

1. Remove product [tube[s]] [vial[s]] from package.
2. [Separate one [tube] [vial] from the others.] Hold the [tube] [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert [tube] [vial] over cat and use open end to part cat's hair.
2. Apply contents of one [tube] [vial] of EasySpot™ [For Cats] [as a spot between the shoulder blades] [as a stripe, starting high on the back of the cat's neck to in front of the shoulder blades].
3. Squeeze [tube] [vial] firmly to apply all of the solution to the cat's skin.

[Example Flea life cycle diagram – actual may differ slightly]



- [Look at the Label (Look at the Label icon)]

[Easy] [6] [Six-] [Step] EasySpot™ [For Cats] [Spot-on] [Squeeze-On] Checklist

1. Read the label completely and follow directions.
2. Weigh your cat.
3. Do NOT use dog products on cats.
4. Do NOT treat with more than one pesticide product at a time.
5. Separate animals after treatment to avoid chance of ingestion.
6. Do NOT split tubes between cats.

[For year round protection, apply EasySpot™ [For Cats] monthly.]

[Cat's Name (Empty blank for owner to fill in name)]

[First [dose] [Treatment] (Empty blank for owner to fill in date)]

[Second [dose] [Treatment] (Empty blank for owner to fill in date)]

[Third [dose] [Treatment] (Empty blank for owner to fill in date)]

[Fourth [dose] [Treatment] (Empty blank for owner to fill in date)]

[Fifth [dose] [Treatment] (Empty blank for owner to fill in date)]

[Sixth [dose] [Treatment] (Empty blank for owner to fill in date)]

[Seventh [dose] [Treatment] (Empty blank for owner to fill in date)]

[Eighth [dose] [Treatment] (Empty blank for owner to fill in date)]
 [Ninth [dose] [Treatment] (Empty blank for owner to fill in date)]
 [Tenth [dose] [Treatment] (Empty blank for owner to fill in date)]
 [Eleventh [dose] [Treatment] (Empty blank for owner to fill in date)]
 [Twelfth [dose] [Treatment] (Empty blank for owner to fill in date)]
 [Visit [web-address] to download a free convenient application for your smartphone for an electronic calendar reminder]
 [Visit [web-address] to download a convenient electronic calendar reminder]

[Calendar stickers [with EasySpot™ [For Cats]]
 [[1] [2] [3] [4] [5] [6] [12] [24]-month] [application tracker]
 [For year-round protection, apply EasySpot™ [For Cats] monthly. Place stickers on your calendar as a reminder to reapply EasySpot™ [For Cats] in 30 days.]
 [It's time for EasySpot™ [For Cats] [!]]
 [Enclosed for your convenience [is] [are] [1] [one] [2] [two] [3] [three] [4] [four][5] [five] [6] [six] [12] [twelve] [24] [twenty-four] sticker[s].] [Place stickers on your calendar every 30 day from initial treatment as a reminder to reapply EasySpot™ [For Cats] every 30 days.]
 [Optional Example graphics for calendar stickers and/or magnets.]

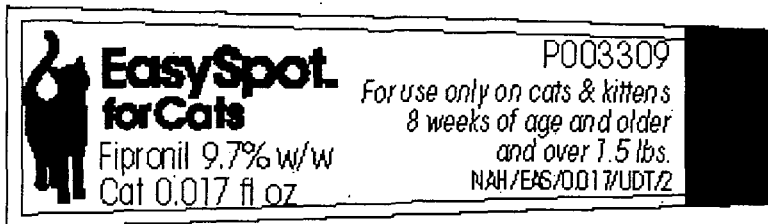


[Monthly Application Reminder Magnet (image of reminder magnet)]
 [Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply EasySpot™ [For Cats]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[END - OPTIONAL EXTERIOR OR INTERIOR PANEL PACKAGE COPY]

[BEGIN TUBE LABEL]

[FRONT OF TUBE]



[BACK OF TUBE]

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read accompanying directions and precautions before using. Use scissors to open.

EPA REG. No. 70585-11

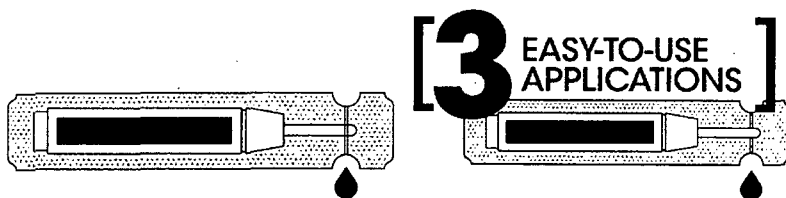
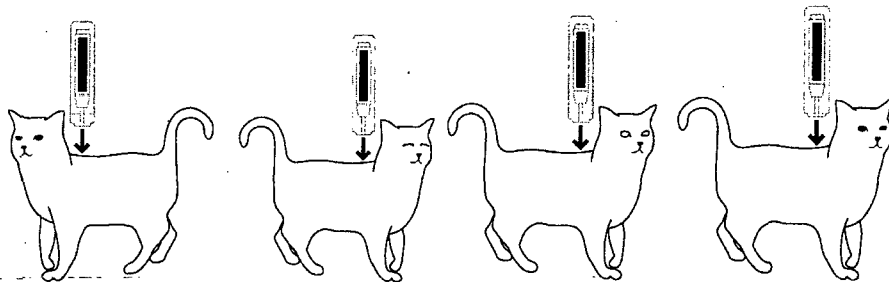
EPA EST. NO. XXXXX-XXX-XXX

{label code}

[END TUBE LABEL]

[OPTIONAL GRAPHICS FOR EXTERIOR OR INTERIOR PANEL PACKAGE:

Example pictograms that may or may not be found on the printed label]



[[1] [2] [4] [5] [6] [12] [24]
EASY-TO-USE
APPLICATIONS]

EPA [Approval Date]