

11556-134

11/18/2013

1/13



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. J. Todd Frank
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

NOV 18 2013

Subject: Label Notification(s) for Pesticide Registration Notice 98-10.

Dear Mr. Frank:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 November 1, 2013, for the following product(s):

K9 Advantix ExtraLarge Dog EPA Reg. No. 11556-134

The Registration Division (RD) has conducted a review of this request for applicability under PR Notice 98-10 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please contact Linda A. DeLuise at 703-305-5428.

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda A. DeLuise".

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-134	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) K9 Advantix Extra Large Dog	PM# Team Number 10	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <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 to NOTIFICATION <input checked="" type="checkbox"/> EPA Reg. No. <u>NOV 18 2013</u> Product Name _____	

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application.

Notification - Explain below. Other - Explain below.

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

Notification per PR Notice 98-10:
 Addition of optional text.

E-mail Contact: todd.frank@bayer.com

Section - III

1. Material This Product Will Be Packaged In:

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"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* 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
 Label Container

4. Size(s) Retail Container

5. Location of Label Directions
 On Label On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph Other _____
 Paper glued
 Stenciled

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name J. Todd Frank	Title Reg. Affairs Consultant	Telephone No. (Include Area Code) 913-268-2585
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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.

2. Signature
J. Todd Frank

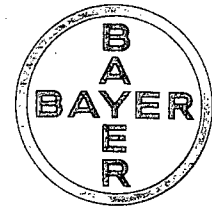
3. Title
Regulatory Affairs Consultant

4. Typed Name
J. Todd Frank

5. Date
11/01/2013

6. Date Application Received (Stamped)

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Bayer HealthCare

Via Federal Express

November 1, 2013

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken/PM 10

Subject: Addition of alternate brand name and optional text:

- K9 Advantix Small Dog; EPA Reg. No. 11556-132
- K9 Advantix Medium Dog; EPA Reg. No. 11556-133
- K9 Advantix Large Dog; EPA Reg. No. 11556-135
- K9 Advantix Extra Large Dog; EPA Reg. No. 11556-134 ✓

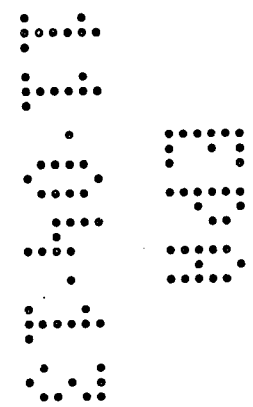
Bayer HealthCare LLC
Animal Health
P.O. Box 390
Shawnee Mission, KS
66201-0390

Dear Mr. Gebken:

Please find enclosed, for the Agency's acceptance, four Applications for Pesticide Notification, one copy of the highlighted label, and ~~one~~ ^{one} copies of the unhighlighted labels for the subject products. **Note:** Similar applications have been made to V. Eagle, Team 1 for the Advantage product line.

As allowed by PR Notice 98-10 Bayer HealthCare LLC Animal Health is adding Alternate Brand Name and other nonsubstantive changes via the enclosed Notifications.

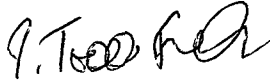
"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."



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If you have any questions, please do not hesitate to call (913) 268-2585.

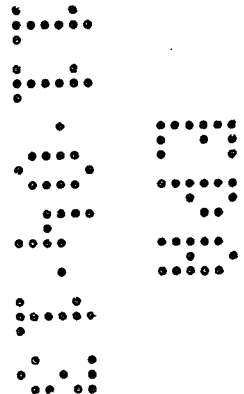
Sincerely,



J. Todd Frank
Regulatory Affairs Consultant
todd.frank@bayer.com

Enclosures:

- 1) K9 Advantix Small Dog - Application w/att.
- 2) K9 Advantix Medium Dog - Application w/att.
- 3) K9 Advantix Large Dog - Application w/att.
- 4) K9 Advantix Extra Large Dog - Application w/att.



S/13

Reason To Issue: Addition of Alternate Brand Name, optional text and minor typographical revisions.

Date: 10/31/13
Supersedes: 07/08/13
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NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language)]

**K9 Advantix® Extra Large Dog Alternate Brand Name: DefenseCare
Flea & Tick Protection Extra Large Dog**

Topical prevention and treatment of fleas, ticks, mosquitoes, biting flies, and lice for monthly use only on dogs and puppies 7 weeks of age and older and weighing over 55 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

NOTIFICATION

DO NOT USE ON CATS

NOV 18 2013

For the Prevention and Treatment of Ticks, Fleas, Mosquitoes, Biting Flies, and Lice on Dogs

[Selected optional claims]

- [For use on dogs and puppies 7 weeks of age and older]
- [A single topical application remains effective for [(a month) (four (4) weeks)]]
- [Convenient, easy to apply topical solution]
- [Once a month topical flea treatment for dogs 7 weeks of age or older]
- [K9 Advantix is indicated for the prevention and treatment of fleas, ticks, biting flies, mosquitoes, and lice on dogs 7 weeks of age and older]
- [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 Lone Star ticks (vector of ehrlichiosis) for up to four (4) weeks]
- [Kills fleas on dogs within 12 hours and continues to prevent infestations for [(a month) (four (4) weeks)]]
- [Kills and repels fleas before they lay eggs]
- [Larval flea stages in the dog's surroundings are killed following contact with a K9 Advantix® treated dog]
- [For the treatment and prevention of flea infestations]
- [One treatment prevents further flea infestations for [(a month) (four (4) weeks)]]
- [Controls existing flea infestations by killing adult fleas]
- [Prevents reinfestations by killing adult fleas before they lay eggs]

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Reason To Issue: Addition of Alternate Brand Name, optional text and minor typographical revisions.

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- [Prevents fleas on treated dogs from infesting (reinfesting) your home.]
- [Treatment with K9 Advantix kills fleas and may reduce the incidence of Flea Allergy Dermatitis (FAD)]
- [Repels and kills mosquitoes for up to four (4) weeks]
- [Repels and kills mosquitoes often before they have a chance to take a blood meal]
- [[(Prevents blood-feeding by) (Kills and repels)] mosquitoes]
- [Remains effective after bathing and swimming [(for a month) (for up to four weeks)]]
- [Repels biting flies]
- [Repels and inhibits blood-feeding by biting flies]
- [Repels and prevents blood-feeding by biting flies]
- [Repels [(annoying)(bothersome)(nuisance)] biting flies]
- [Inhibits [(annoying)(bothersome)(nuisance)] biting flies]
- [[(Prevents)(inhibits)] blood-feeding by biting flies]
- [Kills [(biting) (chewing)] lice]
- [For treatment and prevention of [(biting) (chewing)] lice [infestations]]
- [Controls existing [(biting) (chewing)] lice infestations]
- [5-way protection (against fleas, ticks, biting flies, mosquitoes, and lice)]
- [Treats, prevents and controls [(biting) (chewing)] lice [infestations]]
- [Provides effective control of [(biting) (chewing)] lice [infestations]]
- [Kills [(biting) (chewing)] lice and prevents further infestations]
- [For treatment and prevention of infestations with [(biting) (chewing)] lice]
- [Remains effective after exposure to rain or sunlight]
- [Waterproof]
- [Fragrance free]
- [From the makers of ExpertCare]

Active Ingredients	% By Weight
Imidacloprid	8.8%
Permethrin*	44.0%
Other Ingredients.	<u>47.2%</u>
Total.	100.0%

* cis/trans ratio: Max 55% (±) cis and min 45% (±) trans

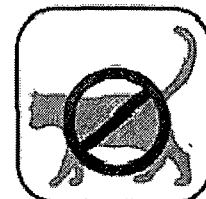
EPA Est. 11556-XXX-X
EPA Reg. No. 11556-134

Reason To Issue: Addition of Alternate Brand Name, optional text and minor typographical revisions.

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Date: 10/31/13
Supersedes: 07/08/13
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[For Directions for Use and other labeling; see supplemental labeling inside.]

See [below] (or) [back panel] for first aid and precautionary statements.



KEEP OUT OF REACH OF CHILDREN

WARNING

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on skin or clothing. Harmful if swallowed. Harmful if absorbed through the skin. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs only. Do not use on animals other than dogs. Do not use on puppies under seven weeks of age. Do not get this product in dog's eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product.

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Side Effects: Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy or agitation) occur, consult your veterinarian or call 1-800-422-9874.

DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.



For consumer questions call 1-800-255-6826. For medical emergencies call 1-800-422-9874.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

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 the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If Swallowed:	<ul style="list-style-type: none"> • 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 the poison control center or doctor. • Do not give anything to an unconscious person.
If On Skin or Clothing:	<ul style="list-style-type: none"> • 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.
HOT LINE NUMBER	

Reason To Issue: Addition of Alternate Brand Name, optional text and minor typographical revisions.

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Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-422-9874 for emergency medical treatment information. For consumer questions call 1-800-255-6826.

NOTE TO PHYSICIAN

Treat the patient symptomatically.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.



HOW TO OPEN

[OPTION 1: INSTRUCTIONS FOR BLISTER PACK]

1. Being careful not to cut close to the blister cavities, take scissors and cut off one section of the card containing a single tube.
2. Take the separated section, and cut into the blister cavity across the small side, close to the cap of the tube.
3. Peel off the foil, and take out the tube.
4. Repeat steps 1 to 3 for each tube.

[OPTION 2: INSTRUCTIONS FOR POUCH PACK]

1. Be sure tube is at bottom of pouch.
2. Using scissors, cut the pouch across the top and remove tube.

HOW TO APPLY

1. Use only on dogs. **DO NOT USE ON CATS** or on other animals.
2. Remove applicator tube from the package.
3. Hold applicator tube in an upright position. Pull cap off tube.

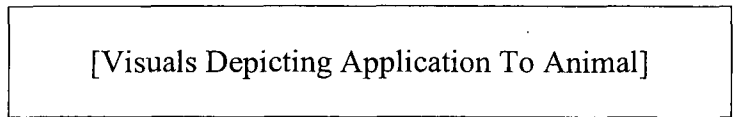
[Visuals Depicting How to Open Applicator Tube]

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4. Turn the cap around and place other end of cap back on tube.
5. Twist cap to break seal, then remove cap from tube.
6. The dog should be standing for easy application. The entire contents of the K9 Advantix[®] tube should be applied evenly to three or four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. Do not get this product in your dog's eyes, or allow your dog to ingest this product.



7. Discard empty tube as described in Storage and Disposal.

PRODUCT INFORMATION

Kills fleas which may cause flea allergy dermatitis (FAD).

K9 Advantix[®] kills existing fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting four (4) weeks. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

Larval flea stages in the dog's surroundings are killed following contact with a K9 Advantix[®] treated dog.

K9 Advantix[®] is waterproof and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

Monthly treatments are required for optimal control and prevention of fleas and ticks.

For dogs over 55 lbs., do not apply more than 1 tube per treatment.

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STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place. Protect from freezing. **Pesticide Disposal and Container Handling:** Nonrefillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency or 1-800-422-9874 for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. 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 profits or values, etc.

Net Contents: XX Tubes each 0.135 fl. oz. (4.0 mL)

[Sample – Not for (Re)Sale]

Manufactured For
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, Kansas 66201 USA

Made in Germany

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Reason To Issue: Addition of Alternate Brand Name, optional text and minor typographical revisions.

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(Label on Individual Tube)

K9 Advantix[®] Extra large Dog

8.8% imidacloprid
44.0% permethrin

0.135 fl. oz. (4.0 mL)

EPA Reg. No. 11556-134

WARNING

Keep out of reach of children
DO NOT USE ON CATS

Read The Entire Label Before Use

BAYER

Lot No. 0000000

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[OPTION 1: Label on blister card; one card containing 1, 2, 3, 4, 5, or 6 tubes]

[OPTION 2: Label on pouch containing one tube]

[Additional label text for OPTION 2: THIS UNIT NOT FOR RETAIL SALE]

K9 Advantix[®] Extra Large Dog

For external use only on dogs and puppies 7 weeks and older and weighing over 55 lbs.

8.8% imidacloprid

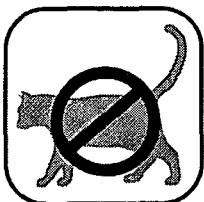
44.0% permethrin

[X] - 0.135 fl. oz. (4.0 mL) Tube(s)

EPA Reg. No. 11556-134

BAYER

Lot No. 0000000



Do Not Use on Cats