

68451-1

5/1/2014

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Megan E. Pletka, Agent
Intervet, Inc.
c/o Technology Services Group, Inc
1150 18th Street NW, Suite 1000
Washington, DC 20036

MAY - 1 2014

Subject: Label Amendment – Restoring Previously Approved Warranty Text Inadvertently
Omitted from the Product Label
Product Name: Deltamethrin 4% Collar
EPA Registration Number: 68451-1
Application Date: April 7, 2014
Decision Number: 489920

Dear Ms. Pletka:

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.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

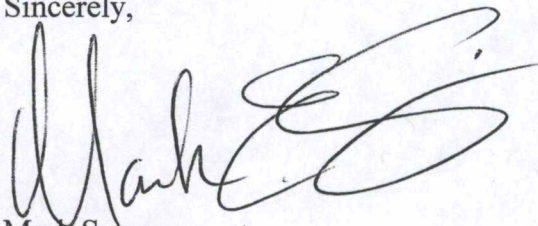
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Label Amendment – Restoring Warranty Statement
Product Name: Deltamethrin 4% Collar
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If you have any questions please contact Michael Walsh by phone at (703) 308-2972 or via email at "walsh.michael@epa.gov".

Sincerely,



Mark Suarez
Product Manager 13
Insecticide Branch
Registration Division
Office of Pesticide Programs

Enclosure

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DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

- | | |
|--|--|
| SCALIBOR® Flea and Tick Collar for Dogs | SCALIBOR® Collar with Deltamethrin |
| SCALIBOR® Flea & Tick Collar for Dogs | SCALIBOR® Collar with 4% Deltamethrin |
| SCALIBOR® Dog Collar for Flea and Tick Control | SCALIBOR® Long Lasting Collar for Dogs |
| SCALIBOR® Dog Collar for Flea & Tick Control | SCALIBOR® Deltamethrin Collar for Dogs |
| SCALIBOR® Collar for Dogs | SCALIBOR® Protector Band for Dogs |
| SCALIBOR® 6-Month Collar for Dogs | SCALIBOR® Tick and Flea Collar for Dogs |
| SCALIBOR® 6-Month Flea and Tick Collar for Dogs | SCALIBOR® 6-Month Flea & Tick Collar for Dogs |
| SCALIBOR® Tick & Flea Collar for Dogs | SCALIBOR® Dog Collar for Tick & Flea Control |
| SCALIBOR® Six Month Collar for Dogs | SCALIBOR® Dog Collar for Tick and Flea Control |
| SCALIBOR® Six Month Flea and Tick Collar for Dogs | SCALIBOR® 6-Month Tick & Flea Collar for Dogs |
| SCALIBOR® Six Month Flea & Tick Collar for Dogs | BandGuard® Collar with Deltamethrin |
| SCALIBOR® Six Month Tick & Flea Collar for Dogs | BandGuard® Collar with 4% Deltamethrin |
| SCALIBOR® Six Month Tick and Flea Collar for Dogs | BandGuard® Long Lasting Collar for Dogs |
| SCALIBOR® 6-Month Tick and Flea Collar for Dogs | BandGuard® Collar for Dogs |
| BandGuard® Flea and Tick Collar for Dogs | BandGuard® Protector Band for Dogs |
| BandGuard® Flea & Tick Collar for Dogs | BandGuard® 6-Month Flea and Tick Collar for Dogs |
| BandGuard® Dog Collar for Flea and Tick Control | BandGuard® Tick & Flea Collar for Dogs |
| BandGuard® Dog Collar for Flea & Tick Control | BandGuard® Dog Collar for Tick & Flea Control |
| BandGuard® Deltamethrin Collar for Dogs | BandGuard® Dog Collar for Tick and Flea Control |
| BandGuard® 6-Month Collar for Dogs | BandGuard® 6-Month Tick & Flea Collar for Dogs |
| BandGuard® Tick and Flea Collar for Dogs | |
| BandGuard® 6-Month Flea & Tick Collar for Dogs | |
| BandGuard® Six Month Collar for Dogs | |
| BandGuard® Six Month Flea and Tick Collar for Dogs | |
| BandGuard® Six Month Flea & Tick Collar for Dogs | |
| BandGuard® Six Month Tick & Flea Collar for Dogs | |
| BandGuard® Six Month Tick and Flea Collar for Dogs | |
| BandGuard® 6-Month Tick and Flea Collar for Dogs | |

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar
See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

ACCEPTED
05012014
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 68451-1

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Deltamethrin 4% Collar
EPA Reg. No: 68451-1

page: 2 of 6
revision date: 4-28-2014

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Intervet Inc (d/b/a Merck Animal Health)
Summit, NJ 07901

Product of France

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

[Product Name] provides full season, up to 6 months protection against fleas and ticks

**PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals**

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

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FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call 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 by mouth 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.
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.
For incidents involving HUMANS , call 1-800-680-9206 For incidents involving ANIMALS , call 1-800-224-5318 EST between the hours of xxx and xxx. Evenings and week-ends call 800-345-4735 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.

Wipe the collar with a damp cloth prior to application. Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. [Product Name] may be used in addition to a lead or constraint collar. Use only one [Product Name] at a time. This collar should be worn continuously. Reapply a new collar every 6 months.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in the accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use of handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx

Universal Product Code Number (Bar Code)

Product of France

OPTIONAL/ALTERNATE LABEL TEXT

[Product Name], containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology.

Fleas (*Ctenocephalides sp.*) on the dog will be killed and those present in the dog's environment that may infest your pet will be killed.

Collar will kill ticks for up to 6 months including: Lone Star tick (*Amblyomma americanum*), Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease.

Kills fleas and ticks for up to 6 months

Long lasting protection for up to 6 months

Protects your dog from (fleas) and (ticks) for up to 6 months

Continuous protection

Kills fleas

Kills ticks (including deer ticks which may transmit *Lyme disease*)

Kills ticks (which may transmit Rocky Mountain Spotted Fever)

Kills ticks (which may transmit anaplasmosis, babesiosis, ehrlichiosis, tularemia, Lyme disease and Southern Tick-Associated Rash Illness (STARI))

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

OPTIONAL/ALTERNATE LABEL TEXT (cont'd)

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection
Not affected by water

Water resistant

Repels mosquitoes for up to six months.

Reduces mosquito bites for up to six months.

Reduces blood feeding by mosquitoes for up to six months.

Protects against mosquito bites for up to six months.

