

773-56

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JUL - 1 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Micah Reynolds, Agent for Intervet, Inc.
c/o Technology Sciences Group Inc.
1150 18th Street N.W., Suite 1000
Washington, D. C. 20036

Subject: Clinafarm Smoke Generator
EPA Registration Number 773-56
Application Date: June 4, 2014
Received Date: June 6, 2014

Dear Mr. Reynolds:

This acknowledges receipt of your Notification submitted in accordance with the provisions of PR Notice 98-10 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

Proposed Notifications

- Add a lot/batch number reference to the canister/bottle sub-label.
- Add Restricted Use Pesticide sub-heading under the Directions for Use heading.

General Comments

Based on a review of the material submitted, this Notification is acceptable.

Should you have any questions or comments concerning this letter, please contact Tom Luminello at (703) 308-8075.

Sincerely,

for Jacqueline Hardy
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Please read instructions on reverse side before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide – Section I

1. Company/Product Number 773-56	2. EPA Product Manager Jacqueline Hardy	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Clinafarm® Smoke Generator	PM# AD/PM-34	
5. Name And Address Of Applicant (Include ZIP Code) Intervet, Inc. (d/b/a Merck Animal Health) 556 Morris Avenue Summit, New Jersey 07901 <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 or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain Below.

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

Submission of Label Notification to add lot number reference statement and inadvertently omitted Directions for Use statement.

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.

Please confirm receipt with Micah Reynolds: mreynolds@tsousa.com, via phone (202) 828-8967, or via fax (202) 872-0745.

Section III

1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container 1.18 oz (33.4 g) 24/box	If "Yes" Unit Packaging wgt. No. per Container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container	4. Size(S) Retail Container 1.18 oz (33.4 g) canisters/carton of 24	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithographed <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Micah T. Reynolds, Technology Sciences Group, Inc.	Title Senior Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8967
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.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant to Intervet, Inc. (d/b/a Merck Animal Health)	
4. Typed Name Micah T. Reynolds	5. Date June 4, 2014	



Technology Sciences Group Inc.
1150 18th Street, Suite 1000
Washington, DC 20036
Direct: (202) 828-8967
Fax: (202) 872-0745
E-Mail: MReynolds@TSGUSA.com

Micah T. Reynolds
Senior Regulatory Consultant

June 4, 2014

Intervet, Inc. (d/b/a Merck Animal Health)
Clinafarm® Smoke Generator, EPA Reg. No. 773-56
Submission of Label Notification

Ms. Jacqueline Hardy (PM-34)
Antimicrobials Division (7510P)
Office of Pesticide Programs (NOTIF)
U.S. Environmental Protection Agency
Document Processing Desk (Room S-4900)
One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202

Dear-Jacqueline:

Technology Sciences Group, Inc., on behalf of Intervet, Inc., is submitting the enclosed label notification for the above referenced product in order to add a lot/batch number reference statement on the canister/bottle sublabel as well add in an inadvertently omitted statement required in the Directions for Use Section due to the product's classification as a Restricted Use Pesticide. In previous label versions, the Restricted Use Pesticide statement has correctly appeared at the top of the front panel; however, as per the requirements of 40 CFR §156.10(i)(2)(i), the use classification statement "Restricted Use Pesticide" had been inadvertently omitted in the Directions for Use section. This enclosed update label intends to remedy the inconsistency and omission. Please find enclosed the following documents supporting this notification:

- 1) EPA Notification Form (EPA Form 8570-1);
- 2) One (1) Copy of the Revised Label with Changes Marked;
- 3) Three (3) Copies of the Revised Product Label.

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at mreynolds@tsqusa.com.

Sincerely,


Regulatory Consultant to Intervet, Inc.

Enclosures
CC: D. Martino; F. Guerino (Intervet)

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(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

556 Morris Avenue
Summit, NJ 07901

EPA Est. No. 39775-EN-01

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[Lot/Batch No.] (Note to reviewer: the lot or batch number may also or alternatively be stamped directly on the outer carton or the individual canisters.)

(OUTER CARTON LABEL (cont'd))

ENVIRONMENTAL HAZARDS
This chemical is toxic to fish.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER - PELIGRO

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wear goggles, face shield, or safety glasses. Wearing long sleeved shirt, long pants, shoes, socks, and chemical resistant gloves (barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton, selection category C). The unignited content of the canister contains a strong oxidizing agent which may cause irreversible eye damage.

PERSONAL PROTECTIVE EQUIPMENT

Some materials that are chemical-resistant to this product are made of barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride or viton. If you want more options, follow the instructions for category C on an EPA chemical-resistance category selection chart.

All handlers must wear long-sleeved shirt and long pants.

Handlers entering the treated area before the ventilation period is over must wear: Long-sleeved shirt and long pants, Shoes plus socks, Goggles, face shield or safety glasses, Chemical-resistant gloves, and a NIOSH-approved respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or an organic-vapor cartridge or canister with any, N, R, P or HE prefilter.

USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

PHYSICAL/CHEMICAL HAZARDS: Flammable. Do not use or store near heat or open flame.

NOTIFICATION
Date Reviewed: JUL - 1 2014
Reviewed By: [Signature]

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**DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL PRECAUTIONS AND RESTRICTIONS

Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application.

For the control of *Aspergillus fumigatus* in cleaned poultry and turkey hatchery equipment prior to the introduction of eggs: such as empty hatcher cabinets, settlers, coolers and egg and chick handling equipment. Imazalil will dramatically reduce the levels of infectious organisms and spores in treated areas. Each canister contains sufficient Imazalil and smoke generating material to cover an enclosure of 400 to 500 cubic feet.

This product may not be used when egg or poultry are present. Treatment of the hatchery equipment should be the final step prior to introduction of the eggs. Do not remove canisters from the container except for immediate use. After equipment has been thoroughly cleaned and disinfected, place a smoke canister of Imazalil on a noncombustible surface. Keep everyone, except applicators, out of treatment site prior to and during application. Before starting, the area to be treated must be closed off to prevent air currents from diluting smoke. Ventilation ducts may be treated, but fans must be shut off. Ignite the wick of the canister. The treatment site must be vacated immediately after lighting the smoke canister. Within 60 seconds, the canister will be through smoking. The smoke must be allowed to settle and contact the surfaces for no less than 1/2 hour but preferably up to at least 12 hours before fumigated equipment and areas are used.

Do not enter or allow others to enter the treated area if smoke is still visible. Do not reenter the unventilated area for at least 12 hours. For ventilated areas, do not enter or allow others to enter the treated areas until the area has been mechanically ventilated (fans) for at least 2 hours. If no mechanical ventilation is used, do not enter or allow others to enter the treated areas for at least 12 hours after application is complete. Early entry is permitted only in an emergency or to operate ventilation equipment, provided that the person is wearing personal protective equipment required for such entry (see PPE requirements on this label.) After the ventilation requirements have been met, workers entering the treatment area to remove canisters must wear chemical resistant gloves.

Post signs at the entrances to the hatchery before the application begins and keep the signs in place until the mechanical ventilation period is over or, if no mechanical ventilation is used, for at least 12 hours after application is complete. The signs must contain the following word in a size that can easily be read: Danger/Peligro, Do Not Enter/No Enter.

STORAGE AND DISPOSAL

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

(Note to reviewer: Product is non-dilutable.)

STORAGE: Store in a cool, dry place. Storage temperature should not exceed 100°F.

PESTICIDE DISPOSAL: Do not contaminate water when disposing of equipment washwaters. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Offer empty canisters for recycling, if available, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities. If outer carton is contaminated and cannot be reused, offer for recycling if available or place in trash, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

NOTICE OF WARRANTY

To the extent consistent with applicable law, Merck Animal Health makes no warranty of merchantability, fitness for any purpose, or otherwise, expressed or implied, concerning this product or its uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label.

NOTIFICATION

Date Reviewed: JUL - 1 2014
Reviewed By: [Signature]

7/8

Clinafarm® SG, EPA Reg No: 773-56

DATE: 6/2/2014

Page 4 of 5

Statement Omission Revision

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

[Product of Janssen Research]

[CLINAFARM® is a registered trademark of Johnson & Johnson]

[CLINAFARM® is a trademark owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.]

[Made in the United Kingdom]

[Take Time, Observe Label Directions - graphic]

NOTIFICATION

Date Reviewed: JUL - 1 2014

Reviewed By: R

8/8

(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

(BOTTLE LABEL)

(UNIT PACK LABEL, FULL TEXT WILL APPEAR ON OUTER SHIPPER CARTON)

RESTRICTED USE PESTICIDE

***Due to Eye Irritation.**

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

CLINAFARM® SMOKE GENERATOR

For the control of *Aspergillus fumigatus* in cleaned poultry and turkey hatchery equipment prior to the introduction of eggs, including empty hatcher cabinets, settlers, coolers and egg and chick handling equipment.

ACTIVE INGREDIENT:

Imazalil (enilconazole): 1-(2-(2,4-Dichlorophenyl)-2-(2-propenyloxy)ethyl)-1H-imidazole..... 14.9% w/w

OTHER INGREDIENTS..... 85.1%

Contains 5 grams Imazalil (enilconazole)..... **TOTAL**..... 100.0% w/w

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

See outer container label for use directions, additional precautionary statements and First Aid.

Net contents: 1.18 oz. (33.4 g)

Manufactured for:

Intervet Inc. (d/b/a Merck Animal Health)
556 Morris Avenue
Summit, NJ 07901

EPA Reg. No. 773-56
EPA Est. No. 39775-EN-01

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[Product of Janssen Research]

[CLINAFARM® is a registered trademark of Johnson & Johnson]

[CLINAFARM® is a trademark owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.]

[Made in the United Kingdom]

[Take Time, Observe Label Directions - graphic]

[Merck Animal Health logo]

[See Bottom for [Lot] [Batch] [Control] [number]]

NOTIFICATION - 1 2014

Date Reviewed:

Reviewed By: TL