



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

NOTIFICATION

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AUG 30 2012

Nancy Huebl
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173

Subject: **Notification:** adding alternate brand name "ClariFly Add-Pack Fly Control for Calves" and adding marketing claim "for use with whole milk or milk replacer" pulled from directions for use, added EPA Reg No. and Lot number RF2163 Dry Concentrate
EPA Reg. No. 2724-816
Your submission dated: 8/8/12

Dear Ms. Huebl:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 8/8/12 for the product EPA Reg No 2724-816. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me @ 703-305-5314 or metzger.autumn@epa.gov.

Sincerely,

Autumn Metzger
Biologist
Insecticide-Rodenticide Branch
Office of Pesticide Programs



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-816	2. EPA Product Manager J. Hebert	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF2163 Dry Concentrate	PM# 7	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200 West Schaumburg, Illinois 60173 <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 _____	

NOTIFICATION
AUG 30 2012

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 of alternate brand name: ClariFly Add-Pack Fly Control for Calves
 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.

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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packagin <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" 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	If "Yes" Unit Packaging wgt. No. per container

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container
10 & 25 lbs

5. Location of Label Directions
 On Label On Label Accompanying Product

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

Section - IV

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

Name Nancy Huebl	Title Senior Registration Specialist	Telephone No. (Include Area Code) (847) 330-5376
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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 statements may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
 (Stamped)

2. Signature <i>Nancy Huebl</i>	3. Title Senior Registration Specialist
4. Typed Name Nancy Huebl	5. Date 08-Aug-12

Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173
847 330 5300
www.wellmarkinternational.com



August 8, 2012



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, Virginia 22202-4501

ATTENTION: J. Hebert, PM 7

SUBJECT: PER PRN 98-10 NOTIFICATION OF ALTERNATE BRAND NAME
FOR RF2163 DRY CONCENTRATE/EPA REG. NO. 2724-816

Dear Mr. Hebert:

Enclosed is a completed EPA Form 8570-1 and 1 copy of revised labeling for the above product. New text is highlighted in red. The label cover sheet details the changes. The alternate brand name is: ClariFly® Add-Pack Fly Control for Calves.

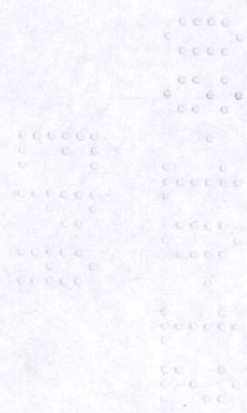
If you have any questions or if I can provide any further assistance, please, call me directly at 847/330-5376. Thank you for your assistance in this matter.

Yours sincerely,
WELLMARK INTERNATIONAL

Nancy Huebl
Sr. Registration Specialist
nhuebl@central.com

enclosure

cc: C. Elmi



4/7

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NOTIFICATION

AUG 30 2012

RF2163 DRY CONCENTRATE

Alternate brand name: ClariFly® Add-Pack Fly Control for Calves

[(Fly larvicide)(fly control) for (beef and dairy) calves]

[(Daily) add-pack for (beef and dairy) calves containing (Dimilin®)(diflubenzuron)(brand name) Insect Growth Regulator (IGR)(a chitin synthesis inhibitor) for continuous feeding during the fly season]

For use with whole milk or milk replacer

[Insect Growth Regulator (IGR) for continuous feeding during the fly season]

[Prevents the development of Horn flies, Face flies, House flies and Stable flies in the manure of (from) treated (beef and dairy) calves (including veal calves).]

[(Stops)(prevents)(growth)(development) of) Horn fly, Face fly, House fly and Stable fly larvae in manure (of)(from) treated (beef and dairy) calves (including veal calves).]

[(Stops)(prevents) emergence of adult Horn flies, Face flies, House flies and Stable flies from manure (of)(from) treated beef and dairy cattle (including veal calves)]

[Breaks the (fly)(flies') life cycle]

[Prevents the (formation)(synthesis) of (chitin) fly larvae's exoskeletons (when they molt)(resulting in their death)]

[(Can be used as) part of a(n) (integrated)(fly)(control)(pest management) program]

[Store in original container, in a cool, dry place]

[Contains (Dimilin®)(diflubenzuron)(brand name)]

ACTIVE INGREDIENT:

Diflubenzuron* (CAS# 35367-38-5)..... 0.16%

OTHER INGREDIENTS99.84%

TOTAL100.00%

*contains 726.4 milligrams of diflubenzuron per pound.

EPA Reg No. 2724-~~XXX~~816

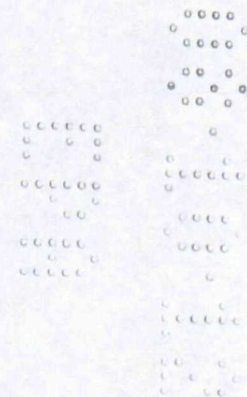
EPA Est. No.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See back/side panel(s) for additional Precautionary Statements

NET WT: xx lbs. (xx kg.)

Lot Number:



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**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION

Harmful if absorbed through skin. Causes moderate 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. Remove and wash contaminated clothing before reuse.

FIRST AID	
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 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. • Call poison control center or doctor for treatment advice.
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-xxx-xxxx for emergency medical treatment information.	

PERSONAL PROTECTIVE EQUIPMENT: Wear long-sleeved shirt and pants, shoes plus socks, and chemical resistant gloves. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER RECOMMENDATIONS

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

ENVIRONMENTAL HAZARDS

This pesticide is toxic aquatic invertebrates. Do not contaminate water when disposing of equipment washwaters.

USE INFORMATION

[(RF2163 Dry Concentrate)(brand name)(this product)] is intended to be added daily to whole milk or reconstituted milk replacers to control house flies, stable flies, horn flies, and face flies which develop in manure of (beef and dairy) calves (including veal calves).

Use [(RF2163 Dry Concentrate)(brand name)(this product)] as part of a(n) [integrated][pest][fly][control][management] program aimed at reducing fly populations in the calf's environment. Consult your [veterinarian][or][retailer] for program recommendations. In order to achieve optimum fly control, use [(RF2163 Dry Concentrate)(brand name)(this product)] in conjunction with [other][Starbar][brand name] premise and on-animal products as well as good management and sanitation practices.

6/7

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DIRECTIONS FOR USE

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

[(RF2163 Dry Concentrate)(brand name)(this product)] contains [(Dimilin®)(diflubenzuron)], [an][insect growth regulator][IGR] which prevents the development of house flies, stable flies horn flies, and face flies in the manure of treated calves, but is not effective against existing adult flies. Start feeding [(RF2163 Dry Concentrate)(brand name)(this product)] early in the spring [(3-4 weeks)(30 days)(1 month)] before flies begin to appear, and continue feeding throughout the summer and into the fall until cold weather (restricts)(stops)(ends) fly activity. In some cases, supplemental fly control measures may be needed in and around [(pastures), (barns), (feedlots) and (calf hutches)] to control adult house and stable flies which [can breed in other decaying (organic)(vegetable) matter or (silage) in the area], or [that migrate in from other locations].

The dosage of [(RF2163 Dry Concentrate)(brand name)(this product)] is proportional to the animal's body weight. Each animal must receive 0.1 oz [(0.00625 lb)] of [(RF2163 Dry Concentrate)(brand name)(this product)] per 100 lbs of body weight, which equates to (0.10 mg diflubenzuron/kg of body weight) (4.54 mg diflubenzuron/100 lbs. of body weight) per day. The product can be mixed by either of the following two methods.

Restriction: Feed calves between the weight of 60-200 pounds not to exceed 0.1 mg/kg per day.

MIXING FOR INDIVIDUAL CALVES

Prepare the whole milk or reconstituted milk replacer for each individual calf. Add the appropriate amount shown below based on the calf's weight, to achieve 0.1 mg/kg.

- ½ teaspoon per 60 lb body weight
- 1 teaspoon per 120 lb body weight
- 1½ teaspoon per 180 lb body weight

Mix thoroughly and feed the entire portion immediately. Repeat daily.

BULK MIXING FOR MULTIPLE CALVES

Thoroughly mix the required amount of [(RF2163 Dry Concentrate)(brand name)(this product)] as shown below into the total amount of whole milk or reconstituted milk replacer needed for the number of calves to be fed, using level measuring cups, teaspoons (tsp) or tablespoons (TBS). Prepare fresh daily to provide the labeled daily intake of (0.10 mg diflubenzuron/kg of body weight)(4.54 mg diflubenzuron/100 lbs. of body weight) per day. Feed each calf an equal portion of the total amount of treated milk.

Average Calf Weight (pounds)	Amount of [(RF2163 Dry Concentrate)(brand name)(this product)] for:					
	5 calves	10 calves	20 calves	40 calves	80 calves	100 calves
75	1 TBS	2 TBS	¼ cup	½ cup	1 cup	1¼ cup
100	4 tsp	8 tsp	1/3 cup	2/3 cup	1 1/3 cup	1 2/3 cup
150	2 TBS	¼ cup	½ cup	1 cup	2 cup	2½ cup
200	8 tsp	1/3 cup	2/3 cup	1 1/3 cup	2 2/3 cup	3 1/3 cup

Important:

Stir or agitate continuously. Feed immediately in containers for individual animals only. DO NOT use bulk feeding containers (i.e. Calf Bars). Failure to properly mix and feed this product may result in underdosing or overdosing of some animals due to settling out of the active ingredient.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in original container in a cool, dry place. Do not contaminate with pesticides or fertilizer.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: (FOR 10/25 LB PAPER OR PLASTIC BAGS): Nonrefillable container. Do not reuse or refill this container. Completely empty bag by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into mixing equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. **(FOR 10 LB PAIL):** Nonrefillable container. Do not reuse or refill this container. Empty container by tapping side to apply contents as directed in the Directions for Use. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration, or if allowed by state and local authorities.

WARRANTY AND LIMITATION OF DAMAGES

Seller warrants that this material conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use and Buyer assumes the risk of any use contrary to such directions. To the extent consistent with applicable law, Seller makes no other express or implied warranty of Fitness or of Merchantability, and no agent of Seller is authorized to do so except in writing and with specific reference to this warranty. In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which claim is made.

In case of emergency or for product use information, call 1-800-xxx-xxxx or visit our web site:

ClariFly is a registered trademark of Wellmark International. Dimilin is a registered trademark of Chemtura Corporation.

Wellmark International
1501 East Woodfield Road 200 W
Schaumburg, IL 60173
[URL]

