

3862-53

11/23/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 23 2009

Ms. Kim Inman
Regulatory Chemist
ABC Compounding Co., Inc.
P.O. Box 16247
Atlanta, GA 30321

Subject: **Lem-O-Dis 19-30**
EPA Registration Number 3862-53
Notification Application Dated October 29 2009
EPA Received Date November 3, 2009

Dear Ms. Inman:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

- Add labeling claims against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/09

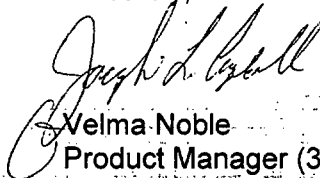
General Comment:

Based on a review of the material submitted, the following comment apply:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions concerning this letter please contact me at Drusilla Copeland at (703) 308-6224.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
CONCURRENTS Division (7510P)

SYMBOL							
SURNAME							
DATE							



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 3862-53	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lem-O-Dis 19-30	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) ABC Compounding Co., Inc. PO Box 16247 Atlanta, GA 30321 <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.)

"Notification of addition of the following text: "Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)." per PR Notice 95-2."

"This notification is consistent with the provisions of PR Notice 95-2 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 18U.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 95-2 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:				2. Type of Container	
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 Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Metal <input type="checkbox"/> Plastic <input checked="" 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 <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55,35,20,5,1 gallon & quart		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" 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 Kim Inman	Title Regulatory Chemist	Telephone No. (Include Area Code) 770-668-9222
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 both under applicable law.		6. Date Application Received (Stamped) _____
2. Signature 	3. Title Regulatory Chemist	
4. Typed Name -Kim Inman	5. Date 10-29-09	



ATLANTA, GEORGIA
 P.O. Box 16247
 Atlanta, GA 30321 0247
 Phone: 770.968.9222
 Toll Free: 800.795.9222
 Fax: 770.968.7281

DALLAS, TEXAS
 Phone: 972.988.9200
 Fax: 972.641.8170

Velma Noble, Product Manager 31
 Regulatory Management Branch I
 Antimicrobials Division (7510C)
 U.S. Environmental Protection Agency
 Ariel Rios Building
 1200 Pennsylvania Ave., NW
 Washington, D.C. 20460

November 2, 2009

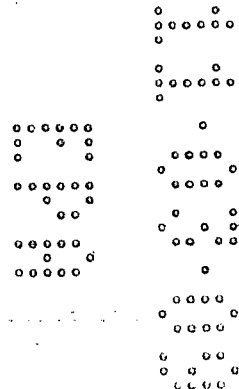
Ms. Noble,

Enclosed are the 8570-1 forms for PR Notice 95-2 for 3862-53 and 3862-112.
 Please send your decision via e-mail to kim.inman@abccompounding.com.

Please note that I never received any acknowledgement of PR Notice 2007-4 (attached), sent to the agency 9-29-08 (3862-53) and 10-27-08 (3862-112). 3862-112 was sent to the wrong Project Manager, but on 9-18-09, Lisa McKelvin acknowledged that the 8570-1 had been forwarded to your department. I have been in e-mail contact with Jacqueline Campbell-McFarlane and Drusilla Copeland about this matter on 10-28-09, 10-20-09, 10-6-09 and 9-15-09. These labels reflect both PR Notices 2007-4 and 95-2.

Thank you,

Kim Inman
 Regulatory Chemist
 ABC Compounding Co., Inc.
 PO Box 16247
 Atlanta, GA 30321
 phone 678-833-2107
 fax 770-960-1059
kim.inman@abccompounding.com





Manufactured by:
ABC Compounding Co., Inc.
P.O. Box 16247
Atlanta, GA 30321-0247
Toll Free 800-795-9222

EPA REG NO. 3862-53
EPA EST NO. 3862-GA-1

ACTIVE INGREDIENTS:
n-alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂,
5% C₁₈) dimethyl benzyl ammonium
chlorides:.....1.6%
n-alkyl (68% C₁₂, 32% C₁₄) dimethyl
ethylbenzyl ammonium
chlorides: 1.6%
OTHER INGREDIENTS:.....96.8%
TOTAL:.....100.0%

Lem-O-Dis 19-30
● **CLEANER** ● **DISINFECTANT** ● **DEODORIZER**
● **FUNGICIDE** ● ***VIRUCIDE**
Desinfectante y desodorante pino

Desinfectante y desodorante Ilmon Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

KEEP OUT OF REACH OF CHILDREN
DANGER
SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.



Net Contents: _____ **Batch No.:** _____

NOTIFICATION
Date Reviewed: 8/23/03
Reviewed By: [Signature]

