



DEPARTMENT OF HEALTH & HUMAN SERVICES

557

HFI-35

7/19/97  
EJS

Public Health Service

Food and Drug Administration  
1141 Central Parkway  
Cincinnati, OH 45202

August 27, 1997

**WARNING LETTER**  
**CIN-WL-97-451**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

G. Allen Andreas, President  
Archer Daniels Midland Company  
4666 Faries Parkway  
P.O. Box 1470  
Decatur, IL 62525

Dear Mr. Andreas:

A pre-license inspection was conducted of the [REDACTED] medicated feed mill located in Hagerstown, Indiana, on April 16 and 17, 1997, by Investigator Charles M. Spyr and representatives of the Office of the Indiana State Chemist and Seed Commissioner.

This inspection revealed that your firm's plant located at Archer Daniels Midland/Animal Health and Nutrition Division, 250 West Clay Street, P.O. Box 609, Lewisburg, Ohio, has sold and shipped Category II Type A medicated articles to [REDACTED] which does not have a valid facility license. The mill had in its possession and/or had produced finished feed from the following Category II Type A medicated articles from your firm: Amprol 25%, Apralan 75, Mecadox 10, Aureo S 700, and Aureomix 500. This is not all-inclusive list of the Category II Type A medicated articles found on the premises.

Removal of Category II Type A medicated articles from your facility is a violation of Section 512(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and causes the new animal drugs to be deemed unsafe for the purposes of Section 501(a)(5) unless you have in your possession an unrevoked, written statement from the consignee, or notice from the Secretary, to the effect that, with respect to the use of such drug in animal feed, such consignee holds a license and has in its possession current approved labeling for such drug in animal feed; or will, if the consignee is not a user of the drug, ship such drug only to a holder of a license.

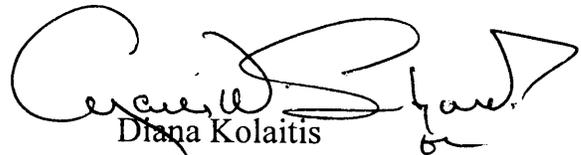
If you have in your possession a written statement which leads you to believe this consignee held a license which entitled it to receive such new animal drugs, we would like to receive a copy of the document.

It is your responsibility to assure that your operation is in compliance with the law. You should assure that each site where your firm handles this type of product adheres to the requirement not to ship to unlicensed or unauthorized parties. You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating the corrections have been made.

Your response should be directed to the Food and Drug Administration, Attention: Leonard Jay Farr, Compliance Officer, 1141 Central Parkway, Cincinnati, Ohio, 45202.

Sincerely yours,



Diana Kolaitis  
District Director  
Cincinnati District Office

LJF/pjk

cc: Steve L. Adams  
Acting Location Manager  
Archer Daniels Midland Company  
Animal Health and Nutrition Division  
250 West Clay Street  
P.O. Box 609  
Lewisburg, OH 45338-0609