



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
FAX: (513) 679-2771

April 28, 2003

**WARNING LETTER**  
**CIN-03-16877**

**VIA FEDERAL EXPRESS**

Robert D. DeGregorio, President  
Land O Lakes Farmland Feed LLC  
1275 Red Fox Road  
Arden Hills, MN 55112

Dear Mr. DeGregorio:

On January 28-29, 2003, the U.S. Food and Drug Administration conducted an inspection of your medicated feed mill located at 767 Old Chillicothe Road, Washington Court House, OH 43160. The inspection revealed that, on December 20, 2002, your firm sold [REDACTED] bags of [REDACTED] (roxarsone 20%) a Category II – Type A Medicated Article to a feed mill that does not have a valid FDA Medicated Feed Mill License. Your firm's failure to establish adequate controls to prevent such illegal distribution of Category II – Type A Medicated Articles was reported to the firm on a Form FDA-483, which was provided to Dave Schultz, Plant Manager (copy enclosed).

Pursuant to Section 512(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 360b(a)(1), a new animal drug is deemed unsafe, and therefore, adulterated under Section 501(a)(5), 21 U.S.C. 351(a)(5), if it is removed from a distributor's establishment for use in the manufacture of animal feed, unless at the time of such removal, the distributor has an unrevoked written statement from the consignee of the drug, or notice from the Secretary of Health and Human Services, to the effect that, with respect to the use of such drug in animal feed, such consignee (i) holds a license and possesses current approved labeling for such drug in animal feed or (ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of a license. Your firm had no such written statement on file from the feed mill to which you sold the [REDACTED] bags of [REDACTED] (roxarsone 20%). Accordingly, removal of a Type A Medicated Article from your facility for the manufacture of free-choice feed by the unlicensed feed mill violates Section 501(a)(5) of the Act and causes the new animal drug to be adulterated.

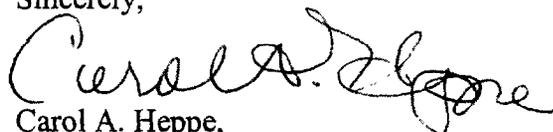
As a distributor of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you distribute are in compliance with the law. This includes ensuring that each site where your firm handles Type A Medicated Articles adheres to the requirement not to ship to unlicensed or unauthorized parties.

You should take prompt action to establish procedures whereby such violations do not recur. Failure to make immediate and lasting corrections may result in regulatory action without further notice, such as seizure and/or injunction.

We acknowledge that your firm recalled remaining portions of the illegal shipment. We also received a February 4, 2003 response letter to the Form FDA-483 from David F. Schultz, Plant Manager (copy attached). This response explains that there was a mistake in placing the order through your Minneapolis purchasing department and states that a restricted product list is maintained and plant personnel will be retrained in the procedures of verifying the type and drug potency. It is apparent from the circumstances which occurred under your operations that this response is not adequate. Your firm needs to establish effective distribution control procedures which will assure that such violations do not recur.

Please advise this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps that you have taken to prevent recurrence of the cited violations. Your response should be directed to Charles S. Price Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237-3097. If you have any questions regarding this letter, you may call Mr. Price at telephone (513) 679-2700 extension 165.

Sincerely,



Carol A. Heppe,  
District Director  
Cincinnati District

Enclosures:

- Form FDA 483
- February 4, 2003 response letter

Cc:

David F. Schultz  
Plant Manager  
Land O'Lakes Farmland Feed  
767 Old Chillicothe Road  
Washington Courthouse, OH 43160

Steve Brown  
Quality Assurance/ Claims Manager  
Land O'Lakes, Inc.  
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