



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

May 8, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2001-021

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

Dear Mr. DeGregorio:

Recently an inspection was made of your medicated feed mill operation located at East Highway 50, Dodge City, Kansas. This inspection was conducted on March 27 & 28, 2001, by an inspector with the Kansas Department of Agriculture, who documented significant deviations from Current Good Manufacturing Practice (CGMP) Regulations for Medicated Feeds (21 CFR, Part 225). Such deviations cause the medicated feeds manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Observations include failure to maintain equipment in such a manner as to prevent cross contamination of medicated feeds; failure to have an adequate clean out procedure to prevent unsafe contamination; failure to perform the required testing of medicated feeds containing Category II medicated articles; failure to insure that appropriate and accurate labeling is used for the medicated feeds produced at this facility; failure of the Master Files to contain mixing times for medicated feeds (dry and liquid).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations, at all of the facilities under your control that manufacture medicated feeds. A copy of the Form FDA 483 is enclosed for your information.

The FDA received a letter from Mr. David Friederich, Plant Manager, dated April 17, 2001, which is his response to the observations listed on the Form FDA 483 issued at the close of the inspection. The corrective actions offered in Mr. Friederich's response were taken into account for the preparation of this letter.

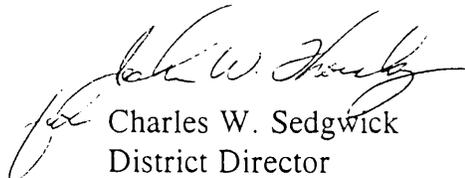
Robert D. DeGregorio, President
Land O'Lakes Farmland Feed, LLC
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You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License for this location, under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). (This letter constitutes official notification under the law.) Based on the results of the March 27/28 inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. If Mr. Friederich's April 17 letter covers the corrective actions necessary to achieve compliance, please let us know. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,


Charles W. Sedgwick
District Director
Kansas City District

Enclosure - Form FDA 483

cc: David Friederich, Plant Manager
Land O'Lakes Farmland Feeds, LLC
P.O. Box 1393
Dodge City, KS 67801