



d1664b

RB 11/13/96

November 12, 1996

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
PO Box 15905
Lenexa, Kansas 66265-5905**WARNING LETTER**

Telephone: (913) 752-2100

Dennis M. Lindsay, Partner
Lindsay Farms
3389 208th Street
Masonville, Iowa 50654

Ref. # - KAN-97-02

Dear Mr. Lindsay:

An inspection of your medicated feed mixer-feeder operation, located at the above address, conducted by an Iowa Department of Agriculture inspector on September 23 and 24, 1996, found continuing significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (21 CFR, Part 225). Such deviations cause medicated feeds being manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Our investigation found: 1) failure to conduct potency assays on at least three representative samples of each feed containing Mecadox 10, a Category II drug, at periodic intervals during the calendar year; 2) failure to calibrate the drug/hand add scale in the past twelve months; 3) failure of records to document the flushing of equipment after use.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for assuring that your overall operation and the products you manufacture and feed to food producing animals are in compliance with the law. At the conclusion of the inspection a Form FDA 483, Inspectional Observations, was issued to and discussed with Jeffery J. Lindsay, Partner. This form is a comprehensive listing of deviations observed by the inspector during the inspection.

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 license 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 September 23 and 24 inspection, evaluated together with the evidence before FDA when the 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.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You may address your reply to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

DISTRIBUTION:

Orig. & enclosure: Addressee
bcc: LF; FF(1927044); HFA-224; HFV-236; HFV-226; HFI-35/DIB(via
FOI); HFC-210; STL-BR(SW-400); RRW; IBRF