



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

4/28/97
EB 4/24/97

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

April 23, 1997

Telephone: (913) 752-2100

WARNING LETTER

Fred Raybourn, President
Western Feed Mills, Inc.
Route 1, Box 596
Cedar Vale, Kansas 67024

Ref. # - KAN-97-014

Dear Mr. Raybourn:

An inspection of your medicated feed mill operation, located at the above address, conducted by an inspector with the Kansas Department of Agriculture on March 6, 1997, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (21 CFR, Part 225). Such deviations cause medicated feeds being 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).

Our inspection found: 1) failure to properly identify and store drugs to maintain their integrity and identity, in that Banminth 48 had expired on 8-1-96, and the drug carbadox 10 and neo-oxy 50/50 was found in inventory but not recorded; 2) failure to have drug inventory records agree with calculated usage in that 20 pounds of Apralan 7.5 was used on 3-1-97 to make a medicated feed, but was not recorded in the drug inventory record; 3) failure to perform the required annual drug assays on free choice medicated minerals containing chlortetracycline, and lasalocid; 4) failure of the master record files to contain copies of approved labeling for all medicated feeds manufactured; 5) failure to have proofread labels dated and initialed by a responsible individual.

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 are in compliance with the law. At the conclusion of the inspection Form FDA 483, Inspectional Observations, was issued to and discussed with you. This form is a comprehensive listing of deviations observed by the inspector during the inspection.

DISTRIBUTION:

Orig.: Addressee

bcc: LF; FF(1910316); HFA-224; HFV-236; HFV-226; HFI-35/DIB(via FOI); HFC-210; RRW; W/RP; IBRF

CRP:rl1

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Western Feed Mills, Inc.

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 facility 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 March 6 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, to inform us of the specific steps you have taken to correct the noted violations and to prevent their recurrence. 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