



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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RB 12/18/00
Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-8905

Telephone: (913) 752-2100

December 6, 2000

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

**WARNING LETTER
KAN #2001-009**

Paul Irvine, President
Farmers Coop Association
3370 Casement Road
Manhattan, KS 66502

Dear Mr. Irvine:

Recently an inspection was made of your medicated feed mill operation located at 3385 Excell Road, Manhattan, Kansas. This inspection was conducted on October 10, 2000, 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, but may not be limited to, the following:

Failure to establish adequate procedures for the receipt, storage, and inventory control of drugs to aid in assuring their identity, strength, quality, and purity [21 CFR 225.42]. Examples include:

Open bags of different medicated articles stored in the same container, with potential for cross contamination through spillage.

Bags of medicated articles being used, with no apparent lot numbers. Lot numbers appeared to have been cut off and discarded.

Discrepancies were found in medicated article inventories regarding weights and lot numbers.

Failure to establish procedures to insure that appropriate and accurate labeling is used for the medicated feeds that you produce [21 CFR 225.80]. Examples include:

“Customer Formula Medicated Beef Feed Containing Monensin (Rumensin)” was found to be labeled as containing 28 g/ton whereas it actually contained 38 g/ton. Additionally, it was labeled as a Type B feed, but was actually a Type C feed.

Obsolete labels for “Customer Formula Medicated Swine Feed Containing Aureomycin” were found mixed in with currently used labels.

Missing withdrawal statements on “Customer Formula Medicated Beef Feed Containing Chlortetracycline”.

Drug labels are not being provided to all customers receiving medicated feeds.

Failure to document that Master Record Files have been verified for accuracy [21 CFR 225.102(b)(1)].

Failure of batch production records to include identification of person(s) responsible for mixing the feed, and to include a statement of actual yield [21 CFR 225.102(b)(2)].

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. We have enclosed a copy of the Form FDA 483 that was issued to Mr. Steve Peterson, Manager, at the conclusion of the inspection.

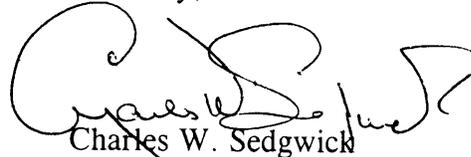
You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill 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 October 10 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. 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.

Paul Irvine, President
Farmers Coop Association
December 6, 2000
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Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is stylized with large, flowing loops and a long horizontal stroke at the end.

Charles W. Sedgwick
District Director
Kansas City District

Enclosure - Form FDA 483

cc: Mr. Steve Peterson, Manager
Farmers Coop Association
3384 Excell Road
P.O. Box 1045
Manhattan, KS 66506