



DEPARTMENT OF HEALTH & HUMAN SERVICES

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11/5/97

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Certified/Return Receipt Requested

October 30, 1997

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

Telephone: (913) 752-2100

WARNING LETTER

R. James Bagnall, President
Arbie Mineral Feed Company, Inc.
409 South Center Street
P.O. Box 594
Marshalltown, Iowa 50158

Ref.# - KAN-98-003

Dear Mr. Bagnall:

An inspection of your medicated feed mill operation located at 404 South Center Street, Marshalltown, Iowa, by an inspector with the Iowa Department of Agriculture, on September 3 through 24, 1997, found 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 are not limited to the following: 1) failure to investigate and document out-of-tolerance reports on various medicated articles such as "Pig Pusher" with CSP 250, "Early Gain", "Litter Sprint", and "Advance Edge", all with Neo-Terramycin; 2) failure of the clean out procedure to document in production records which mixer was used for medicated feeds, and no documentation of the flushing of the pellet mill system; 3) failure to check the [redacted] floor scale for accuracy within the last year; 4) failure to have incoming proofread master labels signed or initialed by a responsible individual; 5) failure to record the actual quantity of medicated feed produced by not documenting the sacking line check weighed bags.

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 distribute are in compliance with the law.

At the conclusion of the inspection a Form FDA 483, Inspectional Observations, was issued to and discussed with Bill Benson, Plant Manager. This form is a comprehensive listing of the inspector's

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observations of deviations found during the inspection. A copy is enclosed for your information.

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 3 through 24 inspection, evaluated together with the evidence before FDA when your 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.

In addition, the inspection found your firm manufacturing a product known as [REDACTED]. This product may be adulterated within the meaning of Section 501(a)(5) of the Act, in that it may be an unapproved new animal drug which is unsafe within the meaning of Section 512. Upon completion of our review of this product we will respond to you by separate letter.

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