



R. Boyle

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Certified/Return Receipt Requested

November 26, 1996

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

WARNING LETTER

James R. Randall, President
Archer Daniels Midland (ADM)
4666 Faries Parkway
Decatur, Illinois 62525

Ref. # - KAN-97-04

Dear Mr. Randall:

An inspection of your firm known as ADM Animal Health and Nutrition Division, 1877 NE 58th Avenue, Des Moines, Iowa, conducted by investigators from this office on October 22 through November 1, 1996, found significant deviations from Current Good Manufacturing Practice (CGMP) Regulations for Type A Medicated Articles (21 CFR, Part 226). Such deviations cause Type A Medicated Articles 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).

Observations include, but are not limited to the following: 1) failure to place a proper expiration date on batches of OTC 50 manufactured by you, since January, 1994, in that your assigned expiry date could exceed the expiry date of the source drug; 2) failure to maintain an adequate drug inventory in that adjustments have been made (for example - 303 lbs., 50 lbs., etc.) with no documented explanation; 3) failure to clean out production and packaging equipment after using an unapproved new drug, leading to drug crossover contamination in another product; 4) failure to conduct mixer studies for all Type A Medicated Articles that would incorporate both liquid and dry mixing times; 5) failure to follow raw material specifications for Terramycin 50, and raw material testing directions in NADA 8-804.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of Type A Medicated Articles 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 Steven E. Dale, Vice President and Manager of Logistics. This form is a comprehensive listing of the investigators' observations of deviations found during the inspection. A copy is enclosed for your information.

Copy: Related Individuals

DISTRIBUTION:

Orig. & Encl.: Addressee

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ADM Animal Health and Nutrition Div.

We have received and reviewed a letter from Mr. Dale dated November 7, which is a response to the Form FDA 483 observations. The letter was reviewed prior to the issuance of this letter. It appears from the letter that proper steps are being taken to correct the noted deviations.

Prompt action should be taken 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 New Animal Drug Applications (NADAs), 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 22 through November 1 inspection, evaluated together with the evidence before FDA when your NADAs were approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of Type A Medicated Articles 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. Until the violations have been corrected and the corrections verified by FDA, the Center for Veterinary Medicine (CVM) will not approve NADAs for the inspected facility.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, to inform us if the November 7 letter will suffice as your response to this letter, or you may expand on that letter with additional information concerning corrections being made. 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

Enclosure - Form FDA 483

cc: Gary Ternus, President

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ADM Animal Health and Nutrition Div.

ADM Animal Health and Nutrition Div.
1877 NE 58th Avenue
Des Moines, IA 50313

Steve Dale, Vice President/Logistic
Manager
ADM Animal Health and Nutrition Div.
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Des Moines, IA 50313