



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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November 17, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David P. Bailey
CEO/President
Moroni Feed Company
P.O. Box 368
Moroni, Utah 84646

Ref. #: DEN-01-7

Dear Mr. Bailey:

Food and Drug Investigators Margaret M. Annes and Brent William Higgs conducted an investigation of your medicated feed mill located at 15 East 1900 S. Feedmill Road in Moroni, Utah on August 31 & September 5, 2000. Significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds [Title 21 Code of Federal Regulations, part 225 (21 CFR 225)] were found. Such deviations cause 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 (the Act).

Our investigation found the following deviations from CGMPs:

- 1) Failure to maintain a daily inventory record for each Type A Medicated Article used as required by 21 CFR 225.42(b)(6).
- 2) Failure to perform a daily comparison of actual vs. theoretical use of each lot or shipment of drug as required by 21 CFR 225.42 (b)(7).
- 3) Failure to perform periodic assays of medicated feeds as required by 21 CFR 225.58(b). Drug assays are not performed on any of the medicated feeds that are produced, including feeds that contain Rofenaid 40, a Category II Type A Medicated Article.
- 4) Failure to maintain Master Record files for each medicated feed as required by 21 CFR 225.102 (b)(1). Specifically, Master Record files are not checked, dated, and signed.

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manufacturing procedures are not defined; assay requirements are not listed; and equipment settings are not referenced.

5) Failure to maintain production records as required by 21 CFR 225.102 (b)(2). The production records are deficient in that the date of production is not written on the record; there is no estimate of the quantity of medicated feed manufactured; no QC check at the end of each day to verify that all production steps were followed and any discrepancies noted and corrected if necessary.

6) Failure to identify each batch as required by 21 CFR 225.102 (b)(5): Each batch or production run of feed is not identified with its own individual batch or production run number, code, date, etc.

7) Failure to test each scale for accuracy as required by 21 CFR 225.30 (b)(4). The Fairbanks scale used to measure the micro ingredients (including Type A Medicated Articles) has only been calibrated [~~XXXX~~] in the past 14 years [~~XXXXXX~~]. The scale is crucial in determining the amount of Type A Medicated Article added to each production run of medicated feed.

The above is not intended as an all-inclusive list of violations. As a manufacturer of medicated feeds, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law. You should take prompt action to correct these 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 your medicated feed license under section 512(m)(4)(B)(ii) of the Act and 21 CFR 515.22(c)(2).

This letter constitutes official notification under the law. The August 31 and September 5, 2000 inspection shows 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. We are enclosing a copy of 21 CFR 225 for your information and use.

Please notify this office, in writing, within 15 working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

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Your response should be directed to Jeannette A. Schmiege, Acting Compliance Officer, at the above letterhead address. If you have questions regarding this letter you may contact Ms. Schmiege at (303)236-3046.

Sincerely,



Thomas A. Allison
District Director

Enclosure: As stated

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