



PURGED RJK

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

October 13, 1999

xc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 02

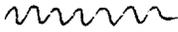
Dr. F. Abel Ponce de Leon
Chair, Animal Science Department
University of Minnesota
305B Haecker Hall
1364 Eckles Avenue
St. Paul, Minnesota 55108

Dear Dr. Ponce de Leon:

An inspection of your medicated feed mill located at Rosemount, Minnesota, conducted by a Minnesota Department of Agriculture investigator on behalf of the Food and Drug Administration on August 12-18, 1999, revealed significant deviations from current Good Manufacturing Practice (GMP) regulations for Medicated Feeds [Title 21, Code of Federal Regulations, Part 225 (21 CFR 225)].

Such deviations cause medicated feeds being manufactured at the facility to be adulterated within the meaning of Sections 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigations found the following deviations:

1. 21 CFR 225.30(b)(4) All scales and metering devices shall be tested for accuracy upon installation and at least once a year thereafter, or more frequently as may be necessary to insure their accuracy. Your liquid metering devices are not checked yearly.
2. 21 CFR 225.42(b)(3) and (4) Bulk drugs shall be identified and stored in a manner such that their identity, strength, quality and purity will be maintained. One bag of  had the label cut out of the bag. A  was stored with the top open. Five medicated articles had exceeded the expiration date. A common scoop was used for all components and was not clean. The storage rack does not prevent contamination of medicated articles or other micro components.

Page Two

Dr. F. Abel Ponce de Leon
October 13, 1999

3. 21 CFR 225.42(b)(5) A receipt record shall be prepared and maintained for each lot of drug received. The receipt record shall accurately indicate the identity and quantity of the drug, the name of the supplier, the supplier's lot number or an identifying number assigned by the feed manufacturer upon receipt which relates to the particular shipment, the date of receipt, the condition of the drug when received, and the return of any damaged drugs. Your records do not record the lot number of the drug, the condition of the drug when received, or the return of damaged goods.
4. 21 CFR 225.42(6) A daily inventory record for each drug used shall be maintained and shall list by manufacturer's lot number or other identifying marks the following information: the quantity of drug on hand at the beginning and end of the work day; the amount of drug used; the batches or production runs of medicated feed in which each drug was used; and the action taken to reconcile any discrepancies in the daily inventory record. You have no daily records.
5. 21 CFR 225.80(b)(2) Labels and labeling, including placards, upon receipt from the printer, shall be proofread against the Master Record File to verify their suitability and accuracy. The proofread label shall be dated, initialed by a responsible individual, and kept for one year after all the labels from that batch have been used. Since Master Record files, batch files stored in the computer, and labeling do not agree, it is obvious that nothing has been proofread or reconciled.

In addition, your firm is manufacturing feeds containing meat and bone meal that may have been produced from ruminants. All feeds containing a protein derived from ruminants must comply with 21 CFR 589.2000. Enclosed is a copy of the regulation and another paper entitled *FDA Guidance for Industry 68*.

The above is not intended to be an all-inclusive list of GMP violations. As a manufacturer of medicated and non-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 GMP violations and you should establish procedures whereby such violations do not recur. Failure to promptly correct these GMP 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 mill license under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 14.115(c)(2).

This letter constitutes official notification under the law. Based on the result of the August 12-18, 1999, inspection, evaluated together with the evidence before FDA

Page Three

Dr. F. Abel Ponce de Leon
October 13, 1999

when the Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feed 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 15 working days of 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 GMP violations and prevent their recurrence. If corrective action cannot be completed within 15 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.

Your response should be directed to Compliance Officer Robert P. Snell at the address indicated on the letterhead.

Sincerely,



Edwin S. Dee
Acting Director
Minneapolis District

RPS/ccl

Enclosures: FDA-483, 8/18/99

FDA Guidance for Industry 68

Medicated Feeds Inspection Report, 8/12-18/99

xc: Gary Backes
Farm Animal Attendant
Agricultural Experiment Station
University of Minnesota
1605 - 160th Street
Rosemount, MN 55068

Jeanine Brannon
Assistant Scientist
Department of Animal Science
University of Minnesota
415A Haecker Hall
1364 Eckles Avenue
St. Paul, MN 55108

Page Four

Dr. F. Abel Ponce de Leon
October 13, 1999

Susan Kubitschek
Administrative Director
Department of Animal Science
University of Minnesota
305A Haecker Hall
1364 Eckles Avenue
St. Paul, MN 55108