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

November 5, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-8

James Huisinga
Vice President
Roseland Elevator
18701 County Road 5 SW
Blomkest, Minnesota 56216

Dear Mr. Huisinga:

An inspection of your medicated feed mill located at Blomkest, MN, conducted by an inspector from the Minnesota Department of Agriculture on behalf of the Food and Drug Administration found significant deviations from Current Good Manufacturing Practice (CGMP) 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 Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The following deviations were noted during the inspection:

21 CFR 225.42(b)(6) -- A daily inventory record for each drug used shall be maintained and shall list by manufacturer's lot number or the feed manufacturer's shipment identification number at least the following information:

- (i) The quantity of the drug on hand at the beginning and end of the work day.

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- (ii) The amount of each drug used.
- (iii) The batches or production runs of medicated feed in which each drug was used.

Your firm does not always record the batch or production run in the drug inventory record and a daily accountability of each drug is not being done. The failure to maintain these records caused significant differences in the records for

21 CFR 225.58(b)(1) – For feeds requiring an approved license for their manufacture and marketing, at least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed at periodic intervals during the calendar year. Your firm has not done drug assays since 1994.

The above is not intended to be an all-inclusive list of CGMP 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 CGMP violations and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP 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 August 2, 1996, inspection, evaluated together with the evidence before FDA when the 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.

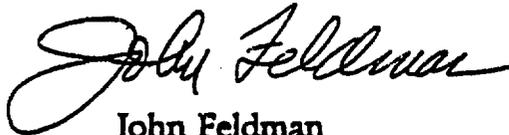
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You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP 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 reply should be directed to Compliance Officer Robert P. Snell, Minneapolis District, at the address indicated on the letterhead.

Sincerely yours,



John Feldman
Director
Minneapolis District

RPS/ccl