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9/24/97
EJF

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

PUNGED *EJF*

September 11, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 61

Charles P. Bobendrier
President
Pipestone Grain Company
318 North Hiawatha, P.O. Box 274
Pipestone, Minnesota 56164

Dear Mr. Bobendrier:

A recent inspection of your medicated feed mill located at Pipestone, MN, by Rick Manthei on behalf of the Food and Drug Administration (FDA) 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).

Our investigation found the following deviations:

1. For feeds requiring an approved mill 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 by approved official methods, at periodic intervals during the calendar year. If a medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided

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the one tested is different from the one(s) previously tested [21 CFR 258.58(b)(1)]. Your firm has not assayed any drugs in the past year.

2. In those instances where medicated feeds are distributed in bulk, complete labeling shall accompany the shipment and be supplied to the consignee at the time of delivery [21 CFR 225.80(b)(3)]. All bulk shipments are not adequately labeled.

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 mill 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 result of the April 16, 1997, inspection, evaluated together with the evidence before FDA when the Form 1900s were 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 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.

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

Sincerely,

A handwritten signature in cursive script, appearing to read "James A. Rahto".

James A. Rahto
Director
Minneapolis District

RPS/ccl