



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

PURGED RAK

September 11, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 50

Charles Bobendrier
President
Pipestone Grain Company
318 North Hiawatha Avenue
Pipestone, Minnesota 56164

Dear Mr. Bobendrier:

An inspection of your medicated feed mill located at Pipestone, MN, conducted by an investigator from the Food and Drug Administration on February 5-6, 1998, found significant deviations from current Good Manufacturing Practice (GMP) regulations for Medicated Feeds [Title 21, Code of Federal Regulation, 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). One product, 22% Lamb Pre-Creep, is adulterated within the meaning of Section 501(a)(6) and misbranded within the meaning of Section 502(a) of the Act.

Our investigation found the following deviations:

1. 22% Lamb Pre-Creep is an adulterated animal feed within the meaning of Section 501(a)(6) of the Act. The newness of an animal drug, including a new animal drug intended for use in or on animal feed, may arise by reason of the newness of a dosage, method or duration or administration or

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application, or any other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug or animal feed containing such drug when used in another dosage, or another method or duration of administration or application, or different condition, is not a new animal drug [21 CFR 510.455(b)]. Lasalocid is not approved as a free choice feed for lambs or sheep and a dosage of 60 g/ton is twice the maximum allowed for lambs or sheep.

2. 22% Lamb Pre-Creep is also misbranded within the meaning of Section 502(a) of the Act. The label declares 30 g/ton lasalocid and the Master Record File has a concentration of 60 g/ton. Analysis of the product found 51.7 g/ton.
3. 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 the one tested is different from the one(s) previously tested [21 CFR 258.58(b)(1)]. Your firm has one analysis for feeds containing neomycin/oxytetracycline, two analyses for feeds containing carbadox, and two analyses for free choice feeds containing lasalocid. More than three feeds were manufactured in 1997 for these feeds.
4. The Master Record File shall include manufacturing instructions or reference thereto that have been determined to yield a properly mixed medicated feed of the specified formula for each medicated feed produced on a batch or continuous operation basis, including mixing steps and mixing times [21 CFR 225.102(b)(1)(iv)]. Your firm's Master Records do not contain mixing steps and mixing times for Lamb Creep Pellets, calf feeds, and 22% Lamb Pre-Creep.
5. Labels and labeling, including placards, upon receipt from the printer shall be proofread against the Master Record File to verify their suitability and

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accuracy [21 CFR 225.80(b)(2)]. The Master Record File for 22% Lamb Pre-Creep has a concentration of 60 g/ton lasalocid. The label declares 30 g/ton.

6. Equipment that is designed to perform its intended function and is properly installed and used is essential to the manufacture of medicated feeds. Such equipment permits production of feeds of uniform quality, facilitates cleaning, and minimizes spillage of drug components and finished product [21 CFR 225.30]. During cold weather, the lines feeding molasses to the horizontal mixer freeze. Molasses is then added through the chute used for micro ingredients (vitamins, minerals, and type A medicated articles). A buildup was noted on the chute that could cause contamination of the next lot of feed.

In addition, your firm is manufacturing feeds containing meat and bone meal that was 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 a 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 514.115(c)(2).

This letter constitutes official notification under the law. Based on the result of the February 5-6, 1998, inspection, evaluated together with the evidence before FDA 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

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are inadequate to assure and preserve the identify, 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 reply should be directed to Compliance Officer Robert P. Snell at the address indicated on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

RPS/ccl

Enclosures: 21 CFR 589.2000
FDA Guidance for Industry 68