



PURGED R7K

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

October 6, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01- 03

John J. Gessell
President
Gessell Feed Mill, Inc.
303 Third Street, P.O. Box 158
Swanville, Minnesota 56382

Dear Mr. Gessell:

An inspection of your medicated feed mill located at Swanville, MN, conducted by a Minnesota Department of Agriculture inspector on behalf of the Food and Drug Administration on August 10, 2000, found significant deviations from Current Good Manufacturing Practice (CGMP) 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).

Our investigation found the following deviations:

1. There are no receipt records for *wavy* and *wavy*. The receipt records do not always show the supplier's lot number, date received, and the condition of the bags. 21 CFR 225.42(b)(5) requires the receiving record to contain the supplier's lot number or an identifying number assigned by the manufacturer upon receipt which relates to the particular shipment, the date received, and the condition of drug when received.
2. The daily drug record is not current and does not accurately show the supplier's lot number or an identifying number assigned by the manufacturer, the quantity of drug on hand at the beginning and the end of each day, the batch or production runs in which each drug was used, a comparison between the actual amount of drug used and the theoretical

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drug usage, and the reconciliation of any discrepancies. 21 CFR 225.42(b)(6) and (7) require the above information.

3. Although three assays for each drug requiring a mill license are done, they are all done at the same time. 21 CFR 225.58(b)(1) requires the assays to be done at periodic intervals during the calendar year.
4. There is no control over the way labels are stored and handled. 21 CFR 225.80(b)(1) requires that labels be handled and stored in a manner that prevents labeling mixups and assures that correct labeling is employed for the medicated feed.
5. The master record file is incomplete and not current. 21 CFR 225.102(b) lists the information required for the master record file.

In addition, it appears that oxytetracycline/chlortetracycline is being used at an unapproved level in turkey feed, that Chlortetracycline/BMD is being used at an unapproved level in swine feed, and that tylosin/BMD is being used in swine feed when this is not an approved combination.

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 August 10, 2000, 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 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

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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, Food and Drug Administration, at the address on the letterhead.

Sincerely,

A handwritten signature in black ink, appearing to read "James A. Rahto", with a long horizontal flourish extending to the right.

James A. Rahto
Director
Minneapolis District

RPS/ccl

jeh