



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

PURGED *PT*

September 19, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 65

Victor Marquardt
Route 2, Box 152
Dodge Center, Minnesota 55927

Dear Mr. Marquardt:

A recent inspection of your medicated feed mill located at Dodge Center, MN, by Wayne Ulrich 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 your 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. 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 the quantity of drug on hand at the beginning and end of the work day. The quantity shall be determined by weighing, counting, or measuring, as appropriate. A theoretical weight is not sufficient. The actual weight must be recorded. Section 225.42 applies to all drugs you use in the preparation of feeds [21 CFR 225.42(b)(6)(i)].

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2. For feeds requiring an approved mill license for their manufacture, 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. You have no assays for feeds containing Tylan 40-Sulfa G [21 CFR 225.58(b)(1)].
3. The original production record or copy thereof shall be prepared by qualified personnel for each batch or run of medicated feed produced and shall be retained on the premises for not less than 1 year. You do not have records for all drugs used in the preparation of feeds [21 CFR 225.102(b)(2)].

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 assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. Enclosed is a copy of the CGMP regulations that apply to your facility (21 CFR 225.1-120).

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 July 30, 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 ensure 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 at the address indicated on the letterhead.

Sincerely,

A handwritten signature in cursive script that reads "James A. Rahto". The signature is written in black ink and is positioned above the printed name.

James A. Rahto
Director
Minneapolis District

RPS/ccl

Enclosure (1)