



DEPARTMENT OF HEALTH AND HUMAN SERVICES

PURGED

Public Health Service

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

June 15, 1999

WARNING LETTER

cc: HFI-35
DWA

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99-32

Dean Beyer
President
Western Consolidated Cooperative
101 Rand Street, PO Box 78
Holloway, Minnesota 56244

Dear Mr. Beyer:

An inspection of your medicated feed mill located at Sunburg, MN, conducted by a Food and Drug Administration investigator on April 14, 15, & 19, 1999, 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 this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigations found the following deviations:

The records required by **21 CFR 225.42(b)(1, 5, 6, & 7)** are inconsistent for Aureo S700 in that the following information was not complete for some of the records reviewed.

1. Name of the manufacturer
2. Name of the distributor
3. Date received
4. Lot number
5. Condition when received
6. Actual amount on hand
7. Difference between the actual and theoretical amount on hand.
8. Explanation for #7.

Three assays were not reported for Aureo S700 during the calendar year 1998 [21 CFR 225.58(b)(1)].

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A live rodent was noted in the drug storage room [21 CFR 225.20(b)(3)].

The building is not maintained in a reasonably clean manner [21 CFR 225.20(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.

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 14, 15, & 19, 1999 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.

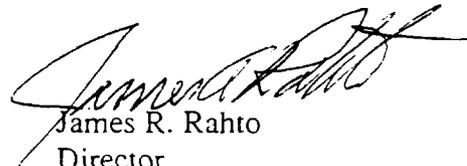
You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be 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 the Food and Drug Administration, Attention Robert P. Snell,
Compliance Officer at the address on the letterhead.

Sincerely yours,

A handwritten signature in black ink, appearing to read "James R. Rahto". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

James R. Rahto
Director
Minneapolis District

cc: Kenneth E. Stalboerger
Branch Manager
Western Consolidated Cooperative
121 Central Avenue
Sunburg, MN 56289