



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

g1228d

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

May 3, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 57

Dale L. Danielson
Manager
Adrian Elevator, Inc.
205 Fourth Street South
Butterfield, Minnesota 56120

Dear Mr. Danielson:

On March 16, 2001, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your animal feed manufacturing operation located at 205 Fourth Street So., Butterfield, MN. This inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000, "Animal Proteins Prohibited in Ruminant Feed" (21 CFR 589.2000). The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and/or distributed by this facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigation found a failure to provide adequate measures to avoid commingling or cross-contamination and failure to maintain adequate written procedures to assure that prohibited animal proteins are not incorporated into feeds that may be used for ruminants. For example, procedures for handling prohibited materials do not specify the amount of flush required. There is no documentation to verify that the amount of flush being used is sufficient. Flush procedures do not specify storage and handling requirements for the flush material. There are no procedures or documentation to verify that production is properly sequenced and that flushes are performed.

The above is not intended to be an all-inclusive list of deviations from the regulations. As a manufacturer of materials intended for animal feed use, you are responsible for ensuring that your overall operation and the products you

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manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulation.

You should take prompt action to correct these violations and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

Please provide this office a written update within 15 working days of receipt of this letter with 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 violations and prevent their recurrence. If corrective action cannot be taken within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

TGP/ccl



Enclosures: FDA-483, 3/16/01

FDA Small Entities Compliance Guide, 21 CFR 589.2000