



Handwritten initials/signature

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

PURGED *RAK*

cc: HFI-35/FOI Staff
DWA

July 24, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-54

Werner Braun
General Manager
Feed Rite, Inc. dba Zip Feed Mills
305 East Sixth Street, Box 5500
Sioux Falls, South Dakota 57102

Dear Mr. Braun:

An inspection of your medicated feed mill located at Sioux Falls, SD, conducted by a Food and Drug Administration investigator on June 26 and 27, 1997, 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).

The following deviations were noted:

1. For feeds requiring an approved 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 the medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided

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the one tested is different from the one(s) previously tested. Your firm has no assays for sulfamethazine in 1996 for AS-700. No assay records for Mecadox could be found when the drug was used as a single ingredient [21 CFR 225.58(b)(1)].

2. Adequate cleanout procedures for all equipment used in the manufacture and distribution of medicated feeds are essential to maintain proper drug potency and to avoid unsafe contamination of feeds with drugs. The delivery trucks are not cleaned between deliveries of feeds [21 CFR 225.65(a)].
3. All equipment shall possess the capability to produce a medicated feed of intended potency, safety, and purity. There are no records demonstrating the computer systems and associated equipment can produce a medicated feed of intended potency, safety, and purity [21 CFR 225.30(b)(1)].

In addition to the cited deviations, your firm has problems with the labeling of custom feeds. These feeds are not exempt from any of the labeling requirements and must contain the same information as branded feed labels.

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 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 June 26 and 27, 1997, 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

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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.

Your reply should be directed to Compliance Officer Robert P. Snell at the address indicated of the letterhead.

Sincerely,


Edwin S. Dee
Acting Director
Minneapolis District

RPS/ccl

xc: Robert Gallaway
General Manager of U.S. Operations
Hubbard Milling
2015 Third Ave.
Mankato, MN 56001

Kerry Nixon
General Manager
Feed Rite Inc. dba Zip Feed Mills
305 East Sixth Street, Box 5500
Sioux Falls, SD 57102