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

PURGED ^{RFK}

July 22, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 53

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

Dear Mr. Braun:

An inspection of your medicated feed mill located at Huron, SD, conducted by a Food and Drug Administration (FDA) investigator on June 30 and July 1, 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. No assays were found for fenbendazole, and sulfamethazine has never been assayed in AS-700 [21 CFR 225.58(b)(1)].

2. The production record shall include the quantity and name of drug components used. Your firm discards the micro ingredient portion of the production record [21 CFR 225.102(b)(2)(ii)].
3. Where the results of assays indicate that the medicated feed is not in accord with label specifications or is not within permissible assay limits as specified in this chapter, investigation and corrective action shall be implemented and an original or copy of the record of such action maintained on the premises. Your firm could not find any record of a follow up on a feed containing neomycin and oxytetracycline (lot no. B6J0903). The assay for oxytetracycline was ~~not~~ declared [21 CFR 225.58(d)].
4. A receipt record shall be prepared and maintained for each lot of drug received. The receipt record shall accurately indicate the identity and quantity of the drug, the name of the supplier, the supplier's lot number or an identifying number assigned by the feed manufacturer upon receipt which relates to the particular shipment, the date of receipt, the condition of the drug when received, and the return of any damaged drugs. You are not recording the condition of the drug as received [21 CFR 225.42(b)(5)].
5. 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 several house cleaning problems. The liquid feed production area is in need of cleaning and the delivery trucks should be cleaned between deliveries. These problems have the potential to contaminate other feeds.

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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 30 and July 1, 1997, inspection, 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.

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

Sincerely,


Edwin S. Dee
Acting Director
Minneapolis District