



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

91333d

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

May 24, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William Dickey
President
Eagle Milling Company, Inc.
14721 W. Main Avenue
Casa Grande, AZ 85222

W/L 48-01

Dear Mr. Dickey:

An inspection of your licensed medicated feed mill located at 14721 W. Main Ave., Casa Grande, AZ, conducted March 14-15, 2001 found continuing, significant deviations from the current Good Manufacturing Practice (cGMP) regulations for licensed Medicated Feeds (Title 21, Code of Federal Regulation, Part 225). Such deviations cause 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" henceforth).

Section 501 (a)(2)(B) of the Act states that a drug shall be deemed adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with cGMP, to assure that such feed meets the requirements of the Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

Our investigators documented that there is no assurance that the methods used in and the controls used for the manufacture of your medicated and non-medicated feeds are in conformity with the cGMPs. These deviations from the regulations were reported to you in the Inspectional Observations, FDA-483, which was issued at the conclusion of the inspection and included the following:

1. Failure to proofread labels and labeling received from the printer against the Master Record File to verify their suitability and accuracy. [21 CFR 225.80 (b)(2)]

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2. Failure to collect and assay at least three representative samples of Carbadox containing feeds during calendar year 2000. [21 CFR 225.58 (b)(1)]
3. Failure to establish procedures for the receipt, storage and inventory control for Type A Medicated Articles (drugs). [21 CFR 225.42 (a)]
4. Failure to investigate and reconcile discrepancies with the recorded use of Carbadox. For example, an employee recorded the use of lot K81215625 while your Drug Usage Record identifies the lot as K8125625. Additionally, the records accompanying the shipment identify the lot number as K80705438, not K8125625. [21 CFR 225.42 (b)(7)]
5. Failure to visually examine incoming shipments of Type A Medicated Articles (drugs) for identity and/or damage. [21 CFR 225.42 (b)(1)]
6. Failure to store, handle and control Type A Medicated Articles (drugs) in a manner to maintain their integrity and identity. For example, several torn or broken bags of drugs were observed in the drug storage area. [21 CFR 225.42 (b)(3)]
7. Incomplete master record files. For example your master record files lack manufacturing instructions and control directions. Examples were found where the same batch of feed was identified by different control numbers. [21 CFR 225.102 (a) and (b)(5)]
8. Failure to review batch records at the end of the working day to determine whether all required product steps have been performed, to identify errors and/or discrepancies and to investigate/correct any mistakes found. [21 CFR 225.102 (b)(4)]
9. Failure to establish written procedures to prevent unsafe carryover of drugs into subsequent production of animal feeds. For example, there was no documentation that flushing took place after the manufacture of a carbadox containing feed you made on 4/14/00. [21 CFR 225.65 (a)]
10. Failure to train and supervise qualified personnel essential for the proper manufacture and control of medicated feeds. [21 CFR 225.10 (b)]

The above identified violations are not intended to be an all-inclusive list of deficiencies at your milling facility. As a producer of medicated and non-medicated feeds, you are responsible for assuring that your establishment is in compliance with all requirements of the federal regulations. Several of the violations noted during this inspection are similar to those noted with previous inspections.

You should take prompt action to correct these deviations, and establish procedures whereby such violations do not recur. Failure to promptly correct these deviations may

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result in regulatory action without further notice. Such action could include, but is not limited to, seizure, injunction and/or notice of opportunity for a hearing on a proposal to withdraw approval of your license. This letter constitutes official notification under the law and provides you an opportunity to correct.

In addition to the specific violations noted above, we are concerned that your company has lost two key individuals (Operations Manger and Plant Manager) and has yet to hire replacement personnel.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific actions 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. Please include copies of any available documentation showing that corrections have been made. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. If you have any questions or clarifications regarding this letter prior to your written response, you can contact Barbara Rincon, Compliance Officer at (949) 798-7739.

Please direct your written response to the attention of :

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food and Drug Administration
19900 MacArthur Blvd., Ste. 300
Irvine, CA 92612

Sincerely,



Alonza Cruse
District Director