



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
HFJ-35 M3189N

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

WARNING LETTER

NOV 10 1999

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Star Milling Company
William R. Cramer, President
P. O. Box 728
Perris, CA 92572

W/L 10-00

Dear Mr. Cramer:

An inspection of your medicated feed mill located at 20767 Highway I-215, Perris, CA 92572, conducted July 13th through July 16th, 1999, found continuing, significant deviations from the current Good Manufacturing Practice (cGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations, Part 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) as follows:

1. Failure to maintain the originals or copies of all results of assays on the premises for a period of not less than one year after distribution of the medicated feed [225.58(c)]. Specifically, you could not provide our investigator with the required assay results for [REDACTED] for 1998 and 1999 and for [REDACTED] and [REDACTED] for 1998.
2. Buildings fail to provide adequate space for the storage of components [225.20(a)(4)(i)]. Specifically, [REDACTED] was stored outside the drug storage room since that room was too small to hold the quantity received.
3. Drug components are not stored in a manner to maintain the integrity and identification of such articles [225.42(b)(3)]. Specifically, several Type A Medicated Articles including [REDACTED] were observed open and/or without original manufacturers' lot number and expiration date.
4. Failure to maintain drug inventory record for each lot or shipment of drug by means of a daily comparison of the actual amount of drug used with the theoretical drug usage [225.42(b)(7)]. Specifically, the theoretical drug

usage recorded on the inventory records for [REDACTED] and [REDACTED] did not reflect actual inventory amounts.

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 previously cited. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may 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.

In addition to the specific violations noted above, we offer the following comments:

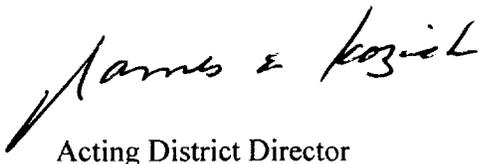
It was noted that your drug storage room has no temperature recording or indicating device. Without such a device, you can not ensure that your drug products are being held to maintain the integrity of the drug product as required by the federal regulations.

It was also observed that finished, sacked feed products lacked the required caution statement "Do not feed to cattle or other ruminants" [21 CFR 589.2000]. While you implemented immediate corrective action for these products, it is your responsibility to ensure that your corrective action prevents recurrence of the deviation.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific actions taken to correct the noted violations and prevent their recurrence. 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. Please direct your written response to the attention of:

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

Sincerely,


Acting District Director