



WARNING LETTER

MAR 22 2000

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Thomas E. Jermin, Sr., President
Templeton Feed and Grain
P. O. Box 127
Templeton, CA 93465

W/L 44-00

Dear Mr. Jermin:

An inspection of your licensed medicated feed mill located at 405 South Main Street, Templeton, CA 93465, conducted January 26th and 27th, 2000, 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 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)]. For example, actual weights for 2 of 3 category I type A medicated articles examined did not agree with recorded inventories.
2. Bulk drug components are not stored in a manner to maintain their identity, strength, quality and purity [225.42(b)(3)]. For example, a partial bag of [REDACTED] was stored in the [REDACTED] container that also contained an open bag of expired [REDACTED].
3. Failure to identify each batch or production run of a medicated feed with its own individual batch or production run number, code date or other suitable identification [225.102(b)(5)].
4. Failure to prepare complete Master Record files/production records for medicated feeds/individual batches of medicated feed produced [225.102]. For example, your Master Record files for [REDACTED] and medicated [REDACTED] do not include the name or quantity of drug used in the manufacture of these products. In addition, individual batch records do not contain a copy or description of the product label, manufacturing instructions, or name and weight percentage of each drug or drug component and each non-drug ingredient used in the manufacture of the medicated feed.

5. Failure to investigate and implement corrective actions after finding that a medicated feed is not within specifications following assay. For example, three assays conducted in 1998 for ██████████ were out of specification. There was no documented investigation or corrective actions implemented as a result of these failures.
6. Failure to verify the suitability and accuracy of labels upon receipt against the Master Record File [225.80(b)(2)]. For example, the label observed in inventory for medicated ██████████ at your firm claims the product contains ██████████ you no longer market the ██████████ containing this drug.

The above-identified violations are not intended to be an all-inclusive list of deficiencies at your milling facility. We acknowledge the response to the FDA-483 you have provided. However, your firm received a Warning Letter in 1994 and was issued a FDA Form 483 at the conclusion of an inspection conducted in 1998 for violations similar to those being cited here. We remind you that it is your continuing responsibility to ensure that your establishment is in compliance with all requirements of the federal laws and regulations. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in further 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.

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. Please provide specific information in your response indicating how your corrective actions will prevent the recurrence of the noted violations. 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

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief