



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

91591d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 2950166

August 1, 2001

John W. Peters, General Manager
Thomas Products LLC
2140 Industrial Avenue
Madera, California 93637

WARNING LETTER

Dear Mr. Peters:

An inspection of your medicated feed manufacturing facility, Thomas Products LLC, located at 2140 Industrial Avenue, Madera, California, 93637, on June 25 through 28, 2001, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon has revealed significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21 Code of Federal Regulations (CFR), Part 225). Such deviations cause the medicated feeds manufactured at your mill to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act. The deviations found during the inspection are as follows:

You failed to perform three assays for Amprol 25% (Amprolium) for calendar year 2000. Three samples of all feeds that require licensing must be analyzed at periodic intervals during the calendar year.

You are failing to always sequence, flush, or otherwise physically clean your manufacturing and delivery equipment between batches of medicated feed to ensure that cross contamination does not occur.

You are failing to maintain a daily theoretical drug inventory of Type A medicated articles your firm uses.

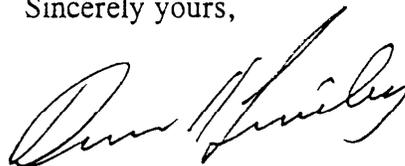
You are failing to provide adequate directions for use for medicated feeds your firm sells. The medicated feed, Amprolium .2 lb/head/day, containing Amprolium does not provide adequate directions for use to the end user. Further, your labeling declares an amount of 40.03 grams of Amprolium per ton of medicated feed. The actual amount of Amprolium in this feed is much higher than declared.

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 approval of your Medicated Feed Mill License under Section 512(m)(4)(B)(ii) of the Act and Title 21, Code of Federal Regulations, Part 514.115(c)(2). (This letter constitutes official notification under the law.) Based on the results of the June 25 through 28, 2001, inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds 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.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met.

Within fifteen days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Russell A. Campbell, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, Ca 94502.

Sincerely yours,



Dennis K. Linsley
District Director

cc:

