



DEPARTMENT OF HEALTH & HUMAN SERVICES

d20456
Public Health Service
Food and Drug Administration

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-52297

September 17, 1998

Arthur D. Van Beek
El Monte Dairy
10410 Avenue 160
Tipton, California 93272-9606

WARNING LETTER

Dear Mr. Van Beek:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on September 2 and 4, 1998, by Food and Drug Administration (FDA) Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On July 13, 1998, you consigned a dairy cow (identified by USDA laboratory report number 273507) for slaughter as human food. This dairy cow was delivered for introduction into interstate commerce by your firm and it was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this animal revealed the presence of tetracycline in the muscle at 2.60 parts per million (ppm); and sulfadimethoxine in the liver at 5.70 ppm and in the muscle at 11.0 ppm. A tolerance level for tetracycline has not been established for the edible tissues of lactating dairy cattle. The tolerance level for sulfadimethoxine for the edible tissues of cattle has been established at 0.01 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions ...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.
2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
3. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.
4. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Med-Pharmex brand of Tetrasol containing tetracycline hydrochloride within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v), and it is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with its approved labeling. Product labeling for Tetrasol states that the drug is to be administered in the drinking water of calves for the treatment of scours and pneumonia. Your practice of placing Tetrasol in a gelatin capsule to create a uterine bolus is an unapproved use for which safety and efficacy have not been established and constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval.

Your use of the drug Animal Health Associates brand of Pen G containing penicillin G procaine is not in conformance with its approved labeling. The labeling for Pen G prescribes a dosage of 1 mL per 100 pounds of body weight and warns against using more than 10 mLs per injection site. Your practice of administering 20 mLs into one site in your dairy cows is an unapproved use for which safety and efficacy have not been established.

El Monte Dairy
Tipton, California

Failure to comply with the label instructions on drugs you use to treat your animals presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Within fifteen (15) days of the receipt of this letter, notify our Fresno resident post 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 John A. Gonzalez, Investigator, United States Food and Drug Administration, 2202 Monterey Street, Suite 104 E, Fresno, California 93721.

Sincerely yours,

*Wayne L. Vaundell, Acting District Director
for PCZ*

Patricia C. Ziobro
District Director
San Francisco District

cc:

