



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
D1135 B

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53329

January 28, 1997

Jack D. Leal
D.C. Leal & Sons Dairy
18682 Idaho Avenue
Lemoore, California 93245

WARNING LETTER

Dear Mr. Leal:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on January 10, 1997, by Food and Drug Administration (FDA) Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On December 5, 1996, you consigned a cull dairy cow (identified by USDA laboratory report number 385950) for sale for slaughter as human food. This dairy cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this animal revealed the presence of tetracycline at levels of 14.00 parts per million (ppm) in the kidney, 5.40 ppm in the liver and 2.00 ppm in the muscle tissues. A tolerance level for tetracycline has been not been established for the edible tissues of dairy cows.

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:

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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 that drugs are used in a manner not contrary to the directions contained in their labeling.
4. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The drug AgriLabs brand of Tetracycline Hydrochloride Soluble Powder 324 that your establishment uses on dairy cows is adulterated under Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(w), 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. Your practice of infusing 1½ ounces of tetracycline hydrochloride into the uterus of fresh dairy cows for puerperal metritis is not in conformance with the prescribed labeling directions provided by your veterinarian. The prescription labeling for Tetracycline Hydrochloride requires a twenty-one day withdrawal time.

You are using the drug Pen-Aqueous brand of penicillin G procaine in a manner not in conformance with its approved labeling. The labeling directions for penicillin G procaine prescribes a dosage of 1 milliliter (mL) per 100 pounds of body weight. A four day withdrawal time is required when the drug is used according to its labeling directions. Your practice of administering two 10 mL intramuscular injections into dairy cows weighing an average of 1430 pounds results in a total dosage of 20 mLs per head per day.

Failure to adhere to prescription and other labeling directions, including required withdrawal times, for drugs you use to treat your dairy cows presents the possibility that illegal residues will occur and is likely the cause of the illegal residues found in the dairy cow you sold for slaughter. Failure to comply with the prescription instructions provided by your veterinarian and other labeling instructions also makes these drugs unsafe.

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.

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Causing the adulteration of drugs after receipt into 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.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) 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 current inspection and in this letter, as well as the inclusion of copies of any available documentation demonstrating that corrections have been made. Please direct your response to John M. Reves, Compliance Officer.

Sincerely yours,

Charles D. Moss
Acting Director

for Patricia C. Ziobro
District Director
San Francisco District

cc:

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