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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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

**CERTIFIED MAIL,
RETURN RECEIPT REQUESTED**

Our Reference: 29-38382

June 20, 1997

Albert Azevedo Dairy
207 Holland Dr.
Turlock, California 95380

WARNING LETTER

Dear Mr. Azevedo:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on April 9, 1997 by Food and Drug Administration (FDA) Investigator Alice Blair, have revealed serious violations of the Federal Food, Drug, and Cosmetic 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 of the Act. On January 15, 1997, you consigned a cull dairy cow (identified by USDA laboratory report number 367732) for sale for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal antibiotic drug residues. USDA analysis of tissues from this animal revealed the presence of sulfadimethoxine in the liver tissue at 0.75 parts per million (ppm) and in the muscle tissue at 0.68 ppm. The tolerance level for sulfadimethoxine in the edible tissue of cattle has been established at 0.1 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.

The Albon brand of sulfadimethoxine boluses that you used to treat your dairy cows are adulterated under Section 501(a)(5) of the Act in that they are new animal drugs within the meaning of Section 201(v) and are unsafe within the meaning of Section 512(a)(1)(B) of the Act since they are not being used in conformance with approved labeling. Labeling for Albon prescribes two boluses followed by one bolus per day for three to four days. The labeling also requires a seven day withdrawal period prior to slaughter for food use. Failure to adhere to the prescribed withdrawal time is likely the cause of the presence of violative levels of sulfadimethoxine in the tissues of the animal you sold for food use.

Your use of the drug Crysticillin a brand of penicillin G procaine is not in conformance with its approved labeling directions. Labeling for penicillin G procaine requires a dose of 1 Ml. per 100 pounds of body weight with no more than 10 Mls. injected into one site. Your practice of administering up to 30 Mls. at one site in your dairy cows results in a dosage in excess of that allowed by the labeling.

Your practice of administering intramuscular injections of the drug Terramycin, a brand of oxytetracycline, and the drug Tylan, a brand of tylosin, in your lactating dairy cows is not in conformance with approved labeling. Labeling for Terramycin and Tylan specifically state the products are not for use in lactating dairy cattle.

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

Your firm has a history of offering cull dairy cows and calves for sale for human food use which have been found to be adulterated with antibiotic drug residues. According to USDA reports, your dairy has delivered other cull dairy cattle which were found by USDA analysis to contain violative levels of antibiotics. As a result, inspections were conducted of your dairy on March 3, 1991 by FDA and on October 1, 1994 by the State of California, Department of Food and Agriculture. During each inspection you were warned that it is illegal to market cull dairy cattle with illegal levels of antibiotics in tissue residues. Two warning letters, dated June 4, 1991 from FDA and October 1, 1994, from the State of California, were sent to you as a result of the violations found during these inspections. Also, the U.S. Department of Agriculture sent you a letter for each instance in which their analysis found violative levels of drug residues. You have failed to take adequate corrective action.

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 include copies of any available documentation demonstrating that corrections have been

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made. Please direct your reply to Alice A. Blair, Investigator, U.S. Food & Drug Administration, P.O. Box 1179, Stockton, CA 95201-1179.

Sincerely yours,

Charles D. Moss, Acting District Director

P.C. Patricia C. Ziobro
District Director
San Francisco District

cc:

