

**DEPARTMENT OF HEALTH & HUMAN SERVICES****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: 29-51426

August 19, 1998

Arthur M. Pedreiro
Antonio M. Pedreiro
11277 Avenue 21½
Chowchilla, California 93610-8980**WARNING LETTER**

Dear Messrs. Pedreiro:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on July 31 to August 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 May 27, 1998, you consigned a dairy cow (identified by USDA laboratory report number 391802) 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 sulfadimethoxine at levels of 10.00 parts per million (ppm) in the liver and 8.60 ppm in the muscle. The tolerance level for sulfadimethoxine for the edible tissues of cattle has been established at 0.10 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 Albon brand of sulfadimethoxine injection 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. Labeling directions for Albon prescribes a dosage of 87.5 milliliters (mLs) for cattle weighing 1400 pounds and warns against releasing animals for slaughter for food within five days of use. Your practice of administering 250 mLs into your dairy cows is likely the cause of the violative levels of sulfadimethoxine found in the tissues of the animal you sold for food use.

Your use of the drug AgriLabs brand of Agri-Cillin containing penicillin G procaine is not in conformance with its approved labeling. The labeling for Agri-Cillin prescribes an intramuscular route of administration only and a dosage of 1 mL per 100 pounds of body weight. The labeling also warns against releasing animals for slaughter for food within ten days of use. Your practice of administering 8 mLs to your dairy cows in an intramammary manner is an unapproved use for which safety and efficacy have not been established.

Your use of the drug AmTech brand of Maxim - 100 containing oxytetracycline hydrochloride is not in conformance with its approved labeling. The labeling for Maxim - 100 specifically states that it is not to be used in lactating dairy cows. Your practice of mixing 500 mLs of Maxim - 100 with one gallon of water to prepare a 60 mL intrauterine wash 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.

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.

Your firm has a history of offering cows and calves for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports during the period December 23, 1992, through June 17, 1994, your firm sold one calf for food use which contained illegal residues of tetracycline. During the same period, you offered three calves which were found by USDA to be CAST positive because of the possible presence of illegal levels of antibiotics. An inspection was conducted at your dairy on September 6, 1994. During the inspection you were warned that it is illegal to market animals that are adulterated with illegal levels of antibiotics. A Warning Letter, dated October 19, 1994, was sent to you as a result of the violations found during that inspection. Also, USDA sent you a letter for each instance in which their analysis found violative levels of drugs. You have failed to take adequate corrective action.

A & T Dairy
Chowchilla, California

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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,



Patricia C. Ziobro
District Director
San Francisco District

cc:

