



DEPARTMENT OF HEALTH & HUMAN SERVICES

M2757

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

Via Federal Express

Our Reference: 29-50831

June 17, 1999

Scott A. Sanders  
SAS Dairy  
2397 West Hackett Road  
Modesto, California 95358

**WARNING LETTER**

Dear Mr. Sanders:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on May 17, 18, and 21, 1999, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon has revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the 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 March 15, 1999, you consigned a dairy heifer (identified by USDA laboratory report number 356763) to be slaughtered for human food. This heifer 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 heifer revealed the presence of sulfamethazine in the liver at 16.00 parts per million (ppm), and in the muscle at 13.00 ppm. Presently, the tolerance level for sulfamethazine in the uncooked edible tissues of cattle is 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 that drugs are used in a manner not contrary to the directions contained in their labeling.
4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug SulfaSURE SR brand sulfamethazine boluses 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 is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling directions for SulfaSURE SR specify that animals intended for human consumption must not be treated within eight days of slaughtering. Your practice of administering sulfamethazine, coupled with an inadequate withdrawal time, presents a possibility that illegal residues will occur and is likely the cause of the illegal residue found in the heifer you sold for food use.

Failure to comply with the label instructions on drugs you use to treat your cows and calves 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 to be sold at an auction where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

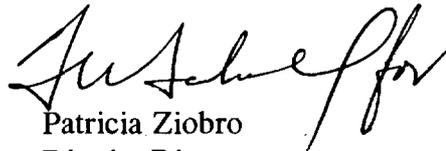
SAS Dairy  
Modesto, California

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Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of January 3, 1992, through March 15, 1999, your firm sold three calves and one heifer which were found to contain illegal drug residues. During this same period you sold six calves which were found to be CAST positive due to the possible presence of harmful levels of antibiotics. An inspection was conducted of your dairy on February 24 and 25, 1993. During the inspection you were warned that it is illegal to market animals with illegal levels of antibiotics. A Warning Letter, dated May 18, 1993, was sent to you as a result of the violations found during the inspection. Also, USDA 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. 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 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 Thomas W. Gordon, Investigator, United States Food and Drug Administration, 2202 Monterey Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,



Patricia Ziobro  
District Director  
San Francisco District

cc:

