



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**

VIA FEDERAL EXPRESS

Our Reference: 29-50275

February 3, 1999

Leo Warmerdam, President
Warmerdam Dairy, Inc.
464 East Fargo Avenue
Hanford, California 93230

WARNING LETTER

Dear Mr. Warmerdam:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on December 29 and 30, 1998, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon 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 of the Act. On July 27, 1998, you consigned a dairy cow (identified by USDA laboratory report number 273530) to be slaughtered as human food. This cow, which was delivered for introduction into interstate commerce by your firm, was adulterated by the presence of an illegal antibiotic drug residue. USDA analysis of tissues from this animal revealed the presence of sulfadimethoxine in the liver at 0.40 parts per million (ppm), and in the muscle at 1.30 ppm. Sulfamethazine was discovered in the liver at 0.16 ppm, and in the muscle at 0.29 ppm. The tolerance levels for sulfadimethoxine and sulfamethazine have been established for the liver and muscle tissues of cattle 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 that drugs are used in a manner not contrary to the directions contained in their labeling.
4. 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.

The Sustain III brand sulfamethazine boluses that your establishment uses to treat lactating 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. Sustain III labeling specifically states, "Do not use in female dairy cattle 20 months of age or older". Your practice of using Sustain III in cattle older than 20 months of age, coupled with a failure to comply with the withdrawal time, is likely the cause of the sulfamethazine residues in the cow you consigned for slaughter.

The Albon brand sulfadimethoxine boluses that you use to treat your dairy cows are adulterated since they are not being used in conformance with approved labeling. Labeling for Albon prescribes two boluses, initially, followed by one bolus per day for three to four days. Your practice of using six boluses for one treatment does not adhere to approved labeling directions and results in a dosage in excess of that allowed by the labeling.

Your use of drugs for treating your dairy cows does not conform to the labeling instructions. Failure to comply with the label instructions on drugs used to treat animals makes the drugs unsafe for use.

Warmerdam Dairy Inc.
Hanford, California

3

We request that you take prompt action to ensure that dairy cows and calves 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 into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

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 February 28, 1989, through July 28, 1998, your firm sold four cows which contained violative levels of penicillin, sulfadimethoxine, sulfamethazine, and streptomycin. During this same period, you sold four calves which were found to be CAST positive by USDA analysis due to the possible presence of violative levels of antibiotics. As a result of the violative residues, inspections were conducted of your dairy on June 27 and July 1, 1991, and on March 2, 1995. During each of those inspections you were warned that it is illegal to market cull dairy cattle which contain illegal levels of antibiotics. A Warning Letter, dated April 3, 1995, was issued to you as a result of these inspections. Also, USDA sent you letters for each of the cull cows and calves in which USDA 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 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 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, Food and Drug Administration, 2202

Warmerdam Dairy Inc.
Hanford, California

4

Monterey Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,

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

cc:

