



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

DIR 17 B

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

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Our Reference: 29-52427

February 24, 1997

Tom L. Kroes  
8509 Avenue 152  
Tipton, California 95320

**WARNING LETTER**

Dear Mr. Kroes:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on January 23, 1997, by Food and Drug Administration (FDA) Investigator Robert J. Anderson 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. On December 12, 1996, you consigned a cull dairy cow (identified by USDA laboratory report number 385953) 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 drug residues. USDA analysis of tissues from this cow revealed sulfamethazine in the liver at 0.97 parts per million (ppm) and in the muscle at 0.68 parts per million (ppm). The tolerance level for sulfamethazine for the edible tissues of cattle is 0.1 ppm.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated due to the presence of drug residues. According to USDA analytical reports, during the period of October 9, 1992, through May 19, 1995, your firm offered one other cow and one calf which contained violative levels of antibiotics. During this same period, you offered one other calf which was found by USDA to be CAST positive because of the possible presence of antibiotics.

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 determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

You are using the drug Pen-Aqueous brand of penicillin G procaine in a manner not in conformance with approved labeling. Labeling for penicillin G procaine prescribes a dosage of 1 milliliter (mL) per 100 pounds of body weight and warns against using more than 10 mL per injection site. Your practice of administering dosages of 30 mLs per day in one site in a cow results in a dosage in excess of that allowed by the labeling.

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.

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

Kroes Dairy  
Tipton, California

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corrections now may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen 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 Robert J. Anderson, Investigator.

Sincerely yours,



for

Patricia C. Ziobro  
District Director  
San Francisco District

cc:

