



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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: 29-39718

August 17, 1998

Manuel Goncalves  
15782 Arroya Avenue  
Dos Palos, California 93620

WARNING LETTER

Dear Mr. Goncalves:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on July 30 through August 4, 1998, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon has 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 May 26, 1998, you consigned a cull dairy cow (identified by USDA laboratory report number 265939) 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 illegal antibiotic drug residues. USDA analysis of tissues from this animal revealed the presence of sulfadimethoxine in the liver at 3.20 parts per million (ppm), and in the muscle at 4.40 ppm. A tolerance level for sulfadimethoxine has been established for the edible tissue of lactating dairy 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 inventory system for determining the quantities of drugs used to medicate your cows and calves.

The Albon brand sulfadimethoxine boluses that you use 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 they 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. The labeling 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 cow you sold for food use.

Your practice of mixing 15 mLs. of the Agri-cillin brand penicillin G procaine injection with 10 mLs. of water to prepare a uterine infusion to medicate your lactating cattle is an unapproved use for which safety and efficacy has not been proven and constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval. Labeling for Agri-cillin specifically states it is to be administered intramuscularly in cows.

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

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 cull dairy 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 of March 25, 1987, through May 26, 1998, your firm sold eight cows and/or calves which contained violative levels of streptomycin, penicillin, tetracycline, neomycin, or sulfadimethoxine. During this same period, you also sold six calves which were found CAST positive by USDA analysis due to the possible presence of violative levels of antibiotics. As a result of the violative residues, an inspection was conducted of your dairy on October 27, 1989. During this inspection you were warned that it is illegal to market cull dairy cattle which contain illegal levels of antibiotics. A Regulatory Letter was issued to you as a result of this inspection. Another inspection was conducted of your dairy on September 18, 1997. During this inspection you were again warned that it is illegal to market cull dairy cattle which contain illegal levels of antibiotics. A Warning Letter was issued to you as a result of this inspection. Also, the U.S. Department of Agriculture has sent you letters for cull cows and calves in which 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, P.O. Box 169, Fresno, California 93707.

Manuel Goncalves Dairy  
Dos Palos, California

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Sincerely yours,

*Patricia C. Ziobro*

Patricia C. Ziobro  
District Director  
San Francisco District

cc:

