



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m2142n

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-54075

October 8, 1998

Robert G. Gioletti
Robert Gioletti and Sons Dairy, Inc.
118 North Blaker Road
Turlock, California 95380

WARNING LETTER

Dear Mr. Gioletti:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on September 10, 1998, by Food and Drug Administration (FDA) Investigator Robert J. Anderson 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. On July 23, 1998, you consigned a dairy cow (identified by USDA laboratory report number 256477) for sale 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 streptomycin in the kidney at 8.00 parts per million (ppm). The tolerance level for streptomycin for the edible tissues of cattle is 2.00 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 those 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.
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 Quartermaster brand of penicillin-dihydrostreptomycin 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) of the Act since it is not being used in conformance with its approved labeling. Labeling for Quartermaster specifies a sixty-day withdrawal time. Your practice of applying an eight-day withdrawal time is not in conformance with approved labeling. Failure to adhere to the recommended withdrawal time is likely the cause of the presence of violative levels of streptomycin in the tissues of the animal you sold for food use. Failure to adhere to labeling directions on a drug presents the likely possibility that illegal residues will occur and makes the drug unsafe to use.

You are using the drug Oxy-Tet 100 brand of oxytetracycline hydrochloride in a manner not in conformance with approved labeling. Oxytetracycline hydrochloride is not approved for use in lactating dairy cows. Your practice of administering 100 mls of Oxy-Tet 100 intravenously in your lactating dairy cows for the treatment of coliform mastitis is not an approved use and will likely result in harmful levels of residues in the tissues of cull cows you sell for food 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.

Robert Gioletti and Sons Dairy, Inc.
Turlock, California

3

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 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, 2202 Monterey Street, Suite 104E, Fresno, California 93721.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

CC:

