



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m3992v

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

Via Federal Express

Our Reference: 2951391

July 25, 2000

Vernal J. Gomes
D. Stanley Gomes
M.F. Gomes and Sons Dairy
20433 Road 28
Tulare, California 93274

WARNING LETTER

Dear Messrs. Gomes:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a cow that originated from your dairy. As a follow-up to USDA's finding, our investigator performed an inspection of your dairy operation located in Tulare, California, on April 27 and 28, 2000. The inspection revealed violations of Section 402 and 501 of the Federal Food, Drug, and Cosmetic Act (the Act).

On March 23, 2000, you consigned a cow, identified with back tag number 93EZ 9389 (USDA laboratory report number 405651), for slaughter as human food at [REDACTED]. [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of the drug sulfadimethoxine in the liver at 28.00 parts per million (ppm), and in the muscle at 26.00 ppm. A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle (Title 21, Code of Federal Regulations, Part 556.640). Your use of sulfadimethoxine in a dairy cow resulted in the illegal drug residue found in the liver and muscle. 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.

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:

You lack an adequate system for determining the medication status of animals you offer for slaughter. Your medication records do not contain the drug and dosage administered and the individual performing the medication of each animal at your dairy.

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.

You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling or your veterinarian's prescription labeling.

You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Sulfadimethoxine Injection – 40% brand sulfadimethoxine 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. The labeling requires a five-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 animal you sold for food use.

Your use of the drug Quartermaster brand penicillin-dihydrostreptomycin is not in conformance with its approved labeling directions. Labeling for Quartermaster requires a milk withdrawal after calving of ninety-six hours (eight milkings). Your practice of withholding milk for only one milking results in adulterated milk being used for human food.

You are using the drug Agripharm brand penicillin G procaine in a manner not in conformance with approved labeling. Labeling directions prescribed by your veterinarian warns against using more than 10 mLs per injection site. Your practice of administering 40 mLs per day in one site in a cow results in a dosage in excess of that allowed by your veterinarian's labeling.

You are using the drug Oxy-tet 100 brand oxytetracycline Hydrochloride in a manner not in conformance with its approved labeling. Labeling directions prescribed by your veterinarian specifically states it is to be infused in the uterus of lactating dairy cattle. Your practice of mixing Oxy-tet 100 oxytetracycline with water as a uterine infusion to medicate your cows is an unapproved use for which safety and efficacy have not been established and requires the submission of a New Animal Drug Application for FDA approval.

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 take prompt action to correct these violations. 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.

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.

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 December 18, 1989, through March 23, 2000, your firm sold eight dairy animals, which were found to contain illegal drug residues. 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.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, 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 Suzanne Schenck, Compliance Officer, at the above address.

Sincerely yours,



Darrell T. Lee
Acting District Director
San Francisco District

cc:

