



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

Via Federal Express

Our Reference: 2939453

February 12, 2001

George and Gloria Soares
Log Haven Dairy
P.O. Box 1327
Hanford, California 93230-1327

WARNING LETTER

Dear Mr. and Mrs. Soares:

A tissue residue report from the United States Department of Agriculture (USDA) and an inspection of your dairy operation located in Hanford, California, on January 22 and 23, 2001 by the U.S. Food and Drug Administration (FDA) have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the 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 September 21, 2000, you consigned a cow, identified with back tag number 686, last three digits (USDA laboratory report number 411618), to be sold as human food. The cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of an illegal drug residue. USDA analysis of tissue samples collected from that animal identified the presence of the drug phenylbutazone in the kidney. A tolerance has not been established for residues of phenylbutazone in the edible tissues of cattle (Title 21 Code of Federal Regulations, Parts 556). Your use of phenylbutazone in a dairy cow resulted in the illegal drug residue found in the kidney.

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 assuring that drugs are used in a manner not contrary to the directions contained in their labeling or your veterinarian's prescription labeling.

2. 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.
3. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Phenylbutazone Injection 20% brand phenylbutazone 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. Your veterinarian prescribed the phenylbutazone in your cows. Labeling on the drug includes a prescribed withdrawal time of fifteen days prior to slaughter. Failure to comply with the withdrawal time is likely the cause of the phenylbutazone residues in the cow you consigned for slaughter.

Furthermore, the drug Oxy-Biotic 100-brand oxytetracycline Hydrochloride that you use to treat your dairy cows is adulterated under 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 Oxy-Biotic 100 specifically states it is to be used to treat non-lactating dairy cattle, and is only to be administered intravenously. 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.

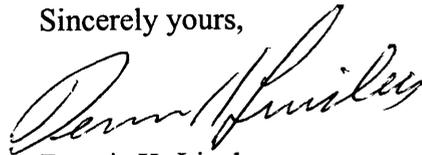
Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should 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.

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 Thomas W. Gordon, Investigator, United States Food and Drug Administration, 2202 Monterey Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,



Dennis K. Linsley
District Director
San Francisco District

cc:

