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

Via Federal Express

Our Reference: 2954813

September 15, 2000

Alvarino F. Alves
Alves Family Dairy
P.O. Box 102
Hilmar, California 95324

WARNING LETTER

Dear Mr. Alves:

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 calf that originated from your dairy. As a follow-up to USDA's finding, our investigator performed an inspection of your dairy operation located in Hilmar, California, on August 24, 2000. The inspection revealed violations of Section 402 and 501 of the Federal Food, Drug, and Cosmetic Act (the Act).

On June 6, 2000, you consigned a calf, identified with back tag number 93 DM 2626 (USDA laboratory report number 391865), to be sold as human food through [REDACTED] [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of the drug gentamicin in the liver at 75.26 parts per million (ppm), in the muscle at 2.72 ppm, and in the kidney at 798.08 ppm. A tolerance has not been established for residues of gentamicin in the edible tissues of cattle (Title 21 Code of Federal Regulations, Part 556.300). Your use of gentamicin in a bob veal calf resulted in the illegal drug residue found in the liver, muscle, and kidney. 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:

1. 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.
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 or your veterinarian's prescription 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 Gentocin brand gentamicin sulfate within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with prescribed labeling. Your veterinarian prescribed the gentamicin sulfate for treatment of bacterial infection in your calves. Labeling on the drug includes a prescribed withdrawal time of eighteen months prior to slaughter. Failure to comply with the withdrawal time is likely the cause of the gentamicin residues in the calf you sold for slaughter.

You are also adulterating the drug Gentocin brand of gentamicin sulfate within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with prescribed labeling. Your veterinarian prescribed the gentamicin sulfate for treatment of bacterial infection in your calves. Your practice of mixing the gentamicin with ten mLs. of penicillin for use in your calves is an unapproved use for which safety and efficacy have not been proven and constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval. Failure to comply with the label instructions on a drug presents the likely possibility that illegal residues will occur and makes the drug unsafe for use.

You are using the drug Hanford's brand penicillin G procaine in a manner not in conformance with approved labeling. Labeling directions warns against using more than 10 mLs per injection site, and no more than one mL per 100 pounds of body weight. Your practice of administering 50 - 60 mLs per day in one site in a cow results in a dosage in excess of that allowed.

You are using the drug Maxim 100 brand oxytetracycline Hydrochloride in a manner not in conformance with its approved labeling. Labeling directions specifically states not for use in lactating dairy cattle. Your practice of mixing Maxim 100 oxytetracycline with water as a uterine infusion to medicate your lactating dairy 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.

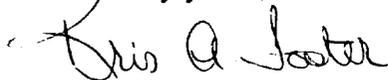
Failure to comply with the label instructions on drugs you use to treat your cows and calves presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not 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,



Kris A. Foster
District Director
San Francisco District

cc:

