



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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

Via Federal Express

Our Reference: 2950801

November 21, 2000

Josua W. Reyneveld
J. W. Reyneveld Dairy Farm, Inc.
4105 Sill Place
Bakersfield, California 93306

WARNING LETTER

Dear Mr. Reyneveld:

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 Arvin, California, on October 26, 2000. The inspection revealed violations of Sections 402 and 501 of the Federal Food, Drug, and Cosmetic Act (the Act).

On July 25, 2000, you consigned a calf, identified with rope number 4 (USDA laboratory report number 391874), for slaughter as human food to [REDACTED]. [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of the drug Streptomycin in the kidney at 2.36 parts per million (ppm), and Sulfamethoxazole in the liver at 0.16 ppm, and in the muscle at 0.06 ppm. A tolerance of 0.50 ppm has been established for residues of Streptomycin in the edible tissues of cattle (Title 21 Code of Federal Regulations, Part 556.640); a tolerance has not been established for residues of Sulfamethoxazole in the edible tissues of cattle. Your use of Sulfamethoxazole in a calf 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:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter. Your medication records do not list all drugs administered to cows and calves.
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.

You are adulterating the drug MP brand sulfamethoxazole 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. Labeling directions prescribed by your veterinarian specify that calves in which sulfamethoxazole has been administered must be withheld for thirty days prior to slaughter. Treating calves with sulfamethoxazole and sending them to slaughter with less than the prescribed 30 day withdrawal time is not in conformance with approved labeling.

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 feeding colostrum taken from treated cows to calves may result in an illegal residue.

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.

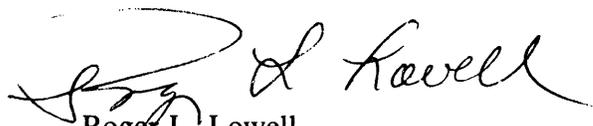
Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

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.

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 October 28, 1992, through July 25, 2000, your firm sold [REDACTED] dairy animals, which were found to contain illegal drug residues. During this same period you sold one calf which was found to be CAST positive due to the possible presence of harmful levels of antibiotics. As a result of the violative residues the Food & Drug Administration conducted an inspection of your dairy on January 26 and 27, 1993. A Warning Letter, dated March 19, 1993, was sent to you as a result of the violations found during the Food & Drug Administration inspection. You have failed to take adequate corrective action. 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 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 Russell A. Campbell, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,



Roger L. Lowell
Acting District Director
San Francisco District

cc:

