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

Via Federal Express

Our Reference: 3003071120

September 17, 2003

Antonio C. Esteves
Dina M. Esteves
Co-owners
Esteves Dairy
8219 Avenue 280
Visalia, CA 93277

WARNING LETTER

Dear Mr. & Mrs. Esteves:

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 July 9, 2003 through July 17, 2003. This inspection revealed serious violations of Sections 402 and 501 of the Federal Food, Drug, and Cosmetic Act (the Act).

On March 31, 2003, you sold one dairy cow, identified with [REDACTED] back tag number [REDACTED], last four digits, for slaughter as human food. USDA analysis of tissue samples (USDA laboratory report number 447116) collected from that animal identified the presence of the drug penicillin in the kidney at 0.10 parts per million (ppm) and in the liver at 0.14 parts per million (ppm). Presently, the tolerance level for penicillin in the uncooked edible tissue of cattle is 0.05 ppm (Title 21 Code of Federal Regulations (CFR), Part 556.510). Your use of penicillin in the animal resulted in the illegal drug residue found in the liver 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 also 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 report the dosages administered, or the name of the individual administering the medication.
2. You lack an adequate system for assuring that animals to which you administer medication are withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs. Your medication records do not contain drug pre-slaughter times.
3. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling or your veterinarian's prescription labeling.
4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Tomorrow (cephapirin benzathine) within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within Section 201(v) of the Act, 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. The manufacturer's labeling states that any animal infused with this product must not be slaughtered for food until 42 days after the latest infusion. You routinely infuse each quarter of the cow's udder with a 10ml syringe, and observe a withdrawal period of approximately seven days before slaughter.

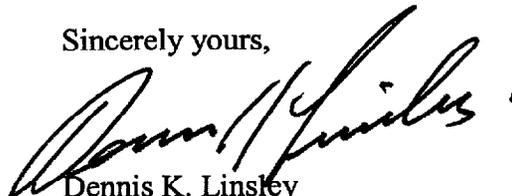
You are also adulterating Pen-Aqueous, Penicillin G. Procaine, 500-ml within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within Section 201(v) of the Act, and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. The veterinary label prescribes a dosage of 30-ml, two times daily in lactating cows, with a withdrawal period of 30 days for meat and five days for milk. You are administering 10-15cc, twice a day, all in one site, for up to seven consecutive days. You do not have a veterinarian's prescription to administer the drug all in one site, up to seven consecutive days. In addition, the veterinary label on the drug specifies a 30 day withdrawal period for meat, not a ten day withdrawal period as you routinely practice. Failure to comply with the label instructions on drugs you use to treat your animals presents the likely possibility that illegal residues will occur in the future and makes the drugs unsafe for use. You must 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. 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 are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify our 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 Marshalette Edwards, Compliance Officer, United States Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,



Dennis K. Linsley
District Director
San Francisco District

cc:

