



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: 2956459

July 25, 2001

Manuel D. Lima, Owner
Manuel Lima Dairy
2618 Reilly Road
Merced, CA 95340

WARNING LETTER

Dear Mr. Lima:

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 dairy cow that originated from your dairy. As a follow-up to USDA's finding, our investigators performed an inspection of your dairy operation in Merced, California, on June 27, 2001. The inspection revealed serious violations of Section 402 and 501 of the Federal Food, Drug, and Cosmetic Act (the Act).

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 May 10, 2001, you consigned a dairy cow, identified with back tag number 3273 (USDA laboratory report number 406796), to be sold for human food through [REDACTED] [REDACTED] USDA analysis of tissue samples collected from that calf identified the presence of the drug sulfadimethoxine in the liver at 4.42 parts per million (ppm), and in the muscle at 2.35 ppm. Presently, the tolerance level for sulfadimethoxine in the uncooked edible tissues of cattle is 0.1 ppm.

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 animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
2. You lack an adequate system for determining the medication status of animals you offer for slaughter. You are not keeping medication records specifying the identity of the drug administered, the dosage administered, and the pre-slaughter withdrawal time.
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. For example, you failed to follow the labeled seven (7) day withdrawal time prior to slaughter for the cow treated with sulfadimethoxine (Albon).
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 Albon brand of 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) of the Act, and is unsafe within the meaning of Section 512 of the Act since it is not being used in accordance with the labeled directions. The labeling for the Albon requires a withdrawal time of seven (7) days after the last treatment. You are observing a withdrawal time of five (5) to six (6) days. Failure to comply with the labeled withdrawal time is likely the cause of the sulfadimethoxine residues in the calf you sold for slaughter.

Failure to comply with the label instructions on drugs you use to treat your animals 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.

Manuel Lima Dairy
Merced, California

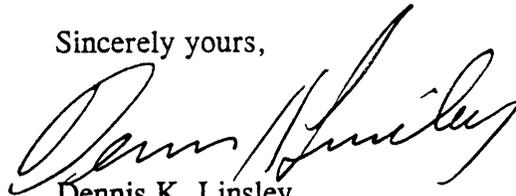
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July 24, 2001

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 Russell A. Campbell, Compliance Officer, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,



Dennis K. Linsley
District Director
San Francisco District

cc:

