



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: 1000123829

January 28, 2004

Larry B. Peterson and Marlene Peterson, Owners
Larry Peterson Dairy
21189 American Ave.
Hilmar, CA 95324

WARNING LETTER

Dear Mr. and Ms. Peterson:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residue in cows that originated from your dairy located at 21189 American Ave., Hilmar, CA 95324. As a follow-up to USDA's finding, our investigators performed an inspection of your dairy operation November 18 through December 2, 2003. This inspection confirmed that you offered animals for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On July 11, 2003, you sold a dairy cow identified with ear tag number [REDACTED], subsequently identified with back tag number [REDACTED] and USDA retain tag # 43071737, for slaughter as human food. USDA analysis of tissue samples (USDA laboratory report number 435782) collected from that animal identified the presence of the drug tetracycline in the kidney at 33.06 parts per million (ppm) and in the muscle at 4.47 ppm.

The tolerance level for tetracycline in kidney of cattle is 12 ppm (Title 21 Code of Federal Regulations (CFR), Part 556.500) and in muscle of cattle is 2 ppm (21 CFR 556.500). Your use of tetracycline in this animal resulted in the illegal drug residues found in the kidney 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 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 investigators noted the following:

1. 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. For example, your veterinary label for Tetracycline Soluble Powder prescribes using the drug in a foot bath, to be applied topically once a week, for the prevention of hairy foot warts. You do nothing to prevent the cows from drinking (ingesting) the medicated water in the foot bath.
2. You lack an adequate inventory/accountability system for determining the quantities of drugs used to medicate your cows and calves.
3. You fail to maintain complete medication treatment records on the dairy cows. For example, your treatment records fail to include the dosage of the drug administered, route of administration for the drug, the person administering the drugs and the withdrawal times for meat and milk.

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.

We are extremely concerned about your dairy's history of delivering for introduction into interstate commerce animals that are adulterated by the presence of illegal drug residues. You were previously cited in a Warning Letter, dated August 22, 1991 for consigning for slaughter as human food a cow that contained illegal drug residues. You should take prompt action to correct the violations observed during FDA's most recent inspection. 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.

Larry Peterson Dairy
Hilmar, California

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January 28, 2004

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
Acting District Director
San Francisco District