



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: 2956566

November 21, 2001

Glenn K. Muranaka, President & General Manager
Meadow Gold Dairies Hawaii
925 Cedar Street
Honolulu, Hawaii 96814-2384

WARNING LETTER

Dear Mr. Muranaka:

A tissue residue report from the United States Department of Agriculture (USDA) and an investigation of Meadow Gold Dairies, 41-330 Waikupanaha Street, Waimanalo, HI, 96795, on October 18, 2001 by the Food and Drug Administration (FDA) have revealed serious violations 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 July 24, 2001, your dairy consigned a cow, identified with ear tag number 3914 (USDA laboratory report number 399095), for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of the drug penicillin in the kidney at 0.37 parts per million (ppm), and in the muscle at 25.30 ppm. A tolerance has been established for residues of penicillin in the edible tissues of cattle at 0.05 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 determining the medication status of animals you offer for slaughter. Your medication records do not contain all drugs and dosages administered to 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.

You are adulterating the drug Quartermaster brand penicillin-dihydrostreptomycin 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. Labeling on the drug requires a withdrawal time of sixty days prior to slaughter. Failure to comply with the withdrawal time is likely the cause of the penicillin residue in the cow you consigned for slaughter.

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.

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.

We acknowledge that Mr. Arnel Gallardo, Farm Operations Manager, indicated to our investigator that Meadow Gold Dairies was ceasing operations in December, 2001 and there are no plans to transfer the dairy operations or start a new dairy. Please confirm in writing that Meadow Gold Dairies is ceasing to operate. Please direct this

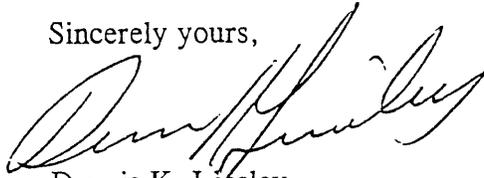
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correspondence to Russell A. Campbell, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502.

If you continue to operate as a dairy or as a supplier of beef for human consumption, 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,



Dennis K. Linsley
District Director

cc:

