



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53536

September 19, 1997

Kenneth L. DeGroot
Sierra View Dairy
13376 Avenue 224
Tulare, California 93274

WARNING LETTER

Dear Mr. DeGroot:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on August 25 and 26, 1997, by Food and Drug Administration (FDA) Investigator Christopher J. Lee have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On May 28, 1997, you consigned a dairy cow (identified by USDA laboratory report number 385972) for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the

presence of illegal antibiotic drug residues. USDA analysis of tissues from this animal revealed the presence of streptomycin in the kidney at 4.40 parts per million (ppm). The tolerance level for streptomycin in the edible tissues of cattle has been established at 2.00 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.
2. You lack an adequate system for assuring that animals to which you administer drugs 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.
4. You lack an adequate inventory system for determining the quantities of drugs you use to medicate your dairy cows and/or calves.

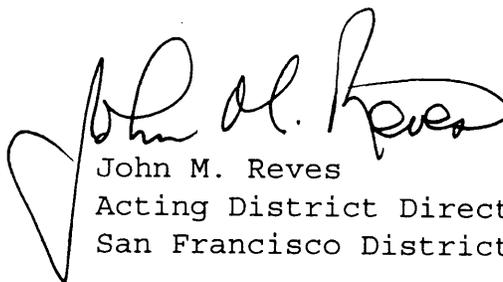
The Quartermaster brand of streptomycin and penicillin that you use to treat your cows is adulterated under Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with its approved labeling. Labeling for Quartermaster prescribes a sixty day withdrawal period prior to slaughter for food use. Failure to adhere to the required withdrawal time is likely the cause of the presence of violative levels of streptomycin in the tissue of the animals you sold for food use.

Sierra View Dairy
Tulare, California

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inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Christopher J. Lee, Investigator, P.O. Box 169, Fresno, CA 93707.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John M. Reves". The signature is written in a cursive style with a large, sweeping initial "J".

John M. Reves
Acting District Director
San Francisco District

cc:

