



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

84206d

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

Via Federal Express

Our Reference: 3003412485

July 9, 2003

Wilfred P. De Groot
Co-Owner
De Groot Dairies #5
15417 Avenue 104
Pixley, CA 93256

WARNING LETTER

Dear Mr. De Groot:

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 investigators performed an inspection of your dairy operation on May 12 and 14, 2003. This inspection revealed serious deviations from the regulations for Tolerances for Residues of New Animal Drugs in Food, Title 21, Code of Federal Regulations (CFR), Part 556. These deviations cause animal drugs to be unsafe under Section 512 of the Federal Food, Drug, and Cosmetic Act (the Act). Use of these drugs in violation of the regulations causes the drugs to be adulterated within the meaning of 501(a) of the Act. Illegal drug residues in food-producing cattle that result from use of unsafe drugs causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act. Further, failure to have systems in place to ensure that cattle with illegal drug residues do not enter the food supply cause the food to be adulterated under Section 402(a)(4) of the Act.

On February 28, 2003, you sold a calf, identified with [REDACTED] Back Tag Number 2357, last four digits, for slaughter as human food. USDA analysis of tissue samples (USDA's Lab Report 447022) collected from that animal identified the presence of the drug sulfadimethoxine in the liver at 0.32 parts per million (ppm) and in the muscle at 0.52 ppm. The tolerance level for sulfadimethoxine in uncooked edible tissue of cattle is 0.1 ppm. 21 C.F.R. § 556.640. Your use of sulfadimethoxine in the animal resulted in the illegal drug residue found in the liver and in the muscle. The investigation revealed that you failed to use the drug sulfadimethoxine, product brand Albon® in conformance with its approved labeling. Failure to use the drug in conformance with its approved labeling causes it to be unsafe within the meaning of Section 512(a)(1)(B) and adulterated within the meaning of Section 501(a)(5) of the Act. The manufacturer's labeling directs that "... [a]nimals should receive an initial dose of 25 mg/lb of the body

weight followed by subsequent daily doses of 12.5 mg/lb of body weight . . .” For example, a 1500 lb cow would receive an initial dosage of 37.5 grams (2 ½ boluses) followed by subsequent daily doses of 18.75 grams (1 ¼ boluses) and a 2000 lb cow would receive an initial dosage of 50 grams (3 ⅓ boluses) followed by subsequent daily does of 25 grams (1 ⅔ boluses). You are administering, without a written prescription from your veterinarian for off-label use, 3-15g boluses (45 grams), 3 times daily for 3 days results in a dosage in excess of that allowed in the labeling. 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.

The investigation also revealed that you lack an adequate system for determining the medication status of animals, and assuring that animals to which you administer medication, such as dairy cows, have been withheld from slaughter for appropriate period of time to deplete potentially hazardous residues of drug. Failure to have such systems in place cause the foods to be adulterated under Section 402(a)(4) of the Act in that the food "has been prepared, packed, or held under insanitary conditions. . . whereby it may have been rendered injurious to health." For example, our investigators observed the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter. Your medication records for your dairy cows do not contain the dosages administered, and the name of the individual performing the medication of each animal at your dairy. In addition, you do not maintain permanent medication records for your calves.
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 consistent with the directions contained in the labeling or your veterinarian's prescription labeling.
4. You are feeding hospital milk to bull calves that could potentially go to slaughter.
5. You lack an adequate system for assuring that the drugs that you use are not expired and that you lack a system which maintains a drug inventory/accountability system.

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.

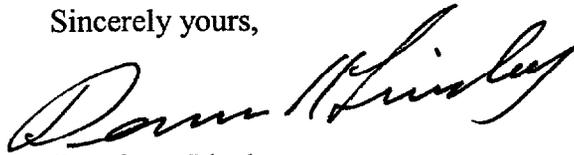
You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act.

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.

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 Lawton W. Lum, 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