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: 29-51328

October 7, 1999

Robert J. Van Grouw, Owner
Robert Van Grouw Dairy
32843 Road 76
Visalia, California 93291

WARNING LETTER

Dear Mr. Van Grouw:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on September 20, 1999, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon 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)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On August 3, 1999, you consigned a dairy cow (identified by USDA laboratory report number 401788) to be slaughtered for human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this cow revealed sulfadimethoxine in the liver at 0.92 parts per million (ppm), and in the muscle at 0.51 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 determining the medication status of animals you offer for slaughter.

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 their labeling.

4. You lack an adequate system for assuring that animals are treated with drugs which have been approved for use in their class of animal or species.

5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Durvet brand of Sulfadimethoxine Injection 40% 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) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling for Sulfadimethoxine Injection 40% specifies that it is to be used for the treatment of bovine shipping fever complex, bacterial pneumonia, foot rot, and calf diptheria. Your practice of using Sulfadimethoxine Injection 40% for the treatment of mastitis in your dairy cows is not a permitted use unless it is by or on the order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and compliant with Title 21 Code of Federal Regulations (CFR) part 530. It is likely that this practice, coupled with an inadequate withdrawal time, was the cause of the illegal residue found in the aforementioned cow.

You are adulterating the drug Pharmacia & Upjohn brand of Quartermaster containing 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) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling for Quartermaster prescribes a withdrawal time of sixty days prior to slaughter. Your practice of administering Quartermaster coupled with a forty-three day withdrawal period prior to slaughter is contrary to directions contained in the labeling.

You are adulterating the drug Durvet brand of Duramycin-324 containing tetracycline hydrochloride soluble powder 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) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling for Duramycin-324 specifies that it is for use in drinking water for swine, calves, and poultry. Your practice of intrauterine insertion of gelatin capsules containing Duramycin-324 into your dairy cows for the treatment of mastitis is not permitted unless it is by or on the order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and compliant with Title 21 CFR part 530.

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.

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.

Within fifteen (15) days of the receipt of this letter, please notify our Fresno office in writing 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 Thomas W. Gordon, Investigator, United States Food and Drug Administration, 2202 Monterey Street, Suite 104E, Fresno, California 93721.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
Director
San Francisco District

cc: [redacted]