



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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: 29-39791

April 28, 1997

Joost Verduyn
Golden West Dairy
12031 Avenue 352
Visalia, California 93291

WARNING LETTER

Dear Mr. Verduyn:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on March 12 and 13, 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 January 14, 1997, you consigned a dairy cow (identified by USDA laboratory report number 382896) 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 gentamicin in the kidney at 2.80 parts per million (ppm). No tolerance level for gentamicin has been established at for the edible tissues of cattle.

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 record keeping 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 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.

The Legacy brand of gentamicin sulfate 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. Your veterinarian prescribed a withdrawal time of eighteen months after the last treatment. Failure to adhere to the prescribed withdrawal time is likely the cause of the illegal residue of gentamicin in the animal you sold for human food use.

You are using the drug Pirsue brand pirlmycin in a manner not in conformance with its approved labeling. Labeling for pirlmycin specifies it is to be administered for two consecutive treatments. Your practice of administering up to three consecutive treatments is an unapproved use for which safety and efficacy have not been proven.

Your use of drugs for treating your dairy cows does not conform to approved labeling instructions. Failure to adhere to the instructions for approved drugs, including withdrawal times and routes of administration, presents the possibility that illegal levels of residues will occur and makes the drugs unsafe to 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.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of July 24, 1989, through January 15, 1990, your firm sold three other dairy cows which contained violative levels of streptomycin, penicillin, and tetracycline. An inspection of your dairy was conducted on March 19, 1990. During this inspection, you were warned that it is illegal to market animals containing violative levels of antibiotics in their edible tissues. A Regulatory Letter, dated June 12, 1990, was sent to you as a result of the violations found during that inspection. Also, the USDA sent you a letter for each instance in which their analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action 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 this 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 Christopher J. Lee, Investigator, P.O. Box 169, Fresno, CA 93707.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

cc: 