



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M30571

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

Via Federal Express

Our Reference: 29-52268

October 8, 1999

Jose M. Xavier, Owner
Xavier Cattle-Holsteins
2892 North Gurr Road
Merced, California 95340

WARNING LETTER

Dear Mr. Xavier:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on May 17 and 20, 1999, by Food and Drug Administration (FDA) Investigator John A. Gonzalez 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 April 26, 1999, you consigned a dairy cow (identified by USDA laboratory report number 391829) 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 gentamicin in the kidney at 5.30 parts per million (ppm). Presently, there is no tolerance level for gentamicin in the uncooked 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 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 Ellsworth brand of Gentadip containing gentamicin sulfate 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 Gentadip specifies the drug is for use in the dipping treatment of turkey hatching eggs only. Your practice of injecting Gentadip into your cows and calves 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, Part 530. It is likely that this practice was the cause of the illegal residue found in the aforementioned cow.

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.

Xavier Cattle-Holsteins
Merced, California

3

Your firm has established a history of offering calves 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 September 11, 1990, through January 17, 1995, you delivered two calves for human food use which were found to contain illegal drug residues. During this same period you delivered four calves which were found to be CAST positive due to the possible presence of harmful levels of antibiotics. An inspection was conducted of your dairy March 9, 1995. During the inspection you were warned that it is illegal to market animals with illegal levels of antibiotics. A Warning Letter, dated May 22, 1995, was sent to you as a result of the violations found during the inspection. Also, 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 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 John A. Gonzalez, Investigator, United States Food and Drug Administration, 2202 Monterey Street, Suite 104E, Fresno, California 93721.

Sincerely yours,

Charles D. Moss
Acting District Director

Pr Patricia C. Ziobro
Director
San Francisco District

cc:

