



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: 29-52679

December 17, 1999

Andy S. Rynsburger
Tom Rynsburger
Adele Rynsburger
Victoria Rynsburger
Rynsburger Dairy
18591 Avenue 192
Strathmore, California 93267-9447

WARNING LETTER

Dear Messrs. and Mesdames Rynsburger:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on November 19 and 24, 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 September 16, 1999, you consigned a dairy cow (identified by USDA laboratory report number 347710) 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 the presence of sulfadimethoxine in the liver at 1.20 parts per million (ppm), and in the muscle at 1.00 ppm. Presently, the tolerance level for sulfadimethoxine in the uncooked edible tissues of cattle is 0.10 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 on their labeling.
4. You lack an adequate system for assuring that animals have been treated only 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.

The drug RXV brand of Sulfadimethoxine Soluble Powder that you use to treat your heifers 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) of the Act since it is not being used in conformance with approved labeling. Labeling directions specify that the product is to be used to medicate dairy calves, dairy heifers, and beef cattle, and animals intended for human consumption must not be treated within seven days of being slaughtered. Your practice of allowing dairy cows to drink from a water trough containing Sulfadimethoxine presents a possibility that illegal residues will occur and is likely the cause of the illegal residue found in the animal you sold for slaughter.

Failure to comply with the label instructions on drugs that you use to treat your cows and calves 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.

Your firm has established a history of offering for sale, for human food use, animals which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of September 21, 1989, through September 16, 1999, your firm sold [REDACTED] dairy cows which were found to contain illegal drug residues. An inspection of your dairy was conducted on March 20, 1996. During the inspection you were warned that it is illegal to market animals with illegal levels of antibiotics. A Warning Letter, dated April 16, 1996, was sent to you as a result of the violations found during the inspection. The State of California conducted a second inspection of your dairy on March 13, 1998. During this inspection you were again warned that it is illegal to market animals with illegal levels of antibiotics. 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, 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 Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,



Patricia Ziobro
District Director
San Francisco District