1998/49

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

441

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-50749

September 19, 1997

David TeVelde, Owner
David TeVelde Dairy
5985-4th Avenue
Hanford, California 93230

WARNING LETTER

Dear Mr. TeVelde:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on August 22 and 26, 1997, by Food and Drug Administration (FDA) Investigator Robert J. Anderson have revealed serious violations of the Federal Food, Drug, and Cosmetic 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 July 1, 1997, you consigned a dairy cow (identified by USDA laboratory report number 385933) for sale 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 drug residues. USDA analysis of tissues from this cow revealed sulfamethazine in the muscle at 4.80 parts per million (ppm) and in the liver at 5.10 ppm. The tolerance level for sulfamethazine in the 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 not contrary to the directions contained in 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 species or class.

5. You lack a drug accountability system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The Sulmet brand sulfamethazine powder that you use to treat your dairy 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(w) 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 for Sulmet states it is to be used in the drinking water of dairy cattle no older than twenty months of age. The labeling also requires a ten day withdrawal period prior to slaughter for food use. Your practice of using Sulmet to medicate dairy cows over twenty months of age is likely the cause of the presence of the violative levels of sulfamethazine in the tissues of the animal you sold for food use.

You're use of the drug Terramycin Soluble Powder brand of oxytetracycline hydrochloride is not in conformance with approved labeling. Terramycin Soluble Powder labeling prescribes a dosage of 10 mg. per pound of body weight, daily, for a maximum of fourteen days in calves. Labeling specifies that it is not to used to medicate lactating dairy cows. Your

practice of filling gelatin capsules with Terramycin powder to create a intrauterine bolus for use in your lactating dairy cows with retained placenta is an unapproved use for which safety and efficacy have not been established and constitutes manufacturing a new animal drug, which requires the submission of a New Animal drug Application for FDA approval.

Failure to adhere to the label instructions for drugs is likely to cause illegal residues 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 and regulations are being met. Failure to achieve prompt corrections now may result in enforcement action without further notice, including seizure and/or injunction.

Your firm has a history of offering cull cows for sale for human use which have been found to be adulterated with antibiotic drug residues. According to USDA reports, during the period of March 26, 1991, through July 1, 1997, your firm delivered four cows for food use which were found to contain illegal drug residues. An inspection was conducted of your dairy on October 23, 1992. During the inspection you were warned that it is illegal to market animals with harmful levels of drugs. A warning letter, dated March 2, 1992, was sent to you as a result of the violations found during that inspection. Also, the U.S. Department of Agriculture sent you a letter for each instance in which its analysis found violative levels of drugs. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen days of the receipt of this letter, 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 Robert J. Anderson, Investigator.

Sincerely yours,

John M. Reves
Acting District Director
San Francisco District

cc: [redacted]