



DEPARTMENT OF HEALTH & HUMAN SERVICES

216636
Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: 510-337-8700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53269

November 15, 1996

Jake Koetsier
Koetsier Dairy
6194 Avenue 228
Tulare, California 93274

WARNING LETTER

Dear Mr. Koetsier:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on October 23 and 25, 1996, by Food and Drug Administration (FDA) Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (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 of the Act. On August 16, 1996, you consigned a cull dairy cow (identified by USDA laboratory report number 367874) for sale for slaughter as human food. This dairy 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 animal revealed the presence of tetracycline at levels of 8.60 parts per million (ppm) in the kidney, 1.00 ppm in the liver and 0.76 ppm in the muscle tissues. A tolerance level for tetracycline has not been established 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 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 animals have been treated only with drugs which have been approved for use in their class of animal or species.
4. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

The drug RXV brand of Tetracycline Soluble Powder 324, tetracycline hydrochloride, that your establishment uses on lactating 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 it is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with its approved labeling. Your practice of mixing 10.08 ounces of tetracycline hydrochloride powder into 40 gallons of water to create a footbath for treatment of footwarts on your dairy cattle is an unapproved use for which safety and efficacy has not been proven.

Labeling for Pen-Aqueous penicillin G procaine prescribes a dosage of 1 milliliter (mL) per 100 pounds of body weight once per day and warns against the administration of more than 10 mLs per injection site. A ten day withdrawal time is required when the drug is used according to its labeling directions. Your practice of administering an initial 10 mL injection followed by a second 15 mL injection results in a total dosage of 25 mLs per head per day into dairy cows weighing an average of 1450 pounds will likely result in illegal levels of drug residues in cows sold for food use.

Your use of drugs for treating your dairy cows does not conform to the labeling instructions. Failure to adhere to the instructions for use is likely the cause of the illegal residues found in the animal you sold for slaughter. Failure to comply with the label instructions on drugs used to treat animals makes the drugs unsafe.

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.

Koetsier Dairy
Tulare, California

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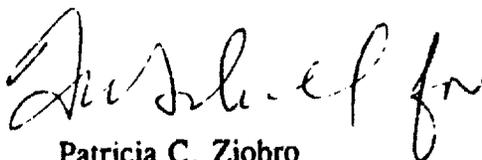
Causing the adulteration of drugs after receipt into interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into 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 into 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 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 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 current inspection and in this letter, as well as the inclusion of copies of any available documentation demonstrating that corrections have been made. Your response should be directed to John M. Reves, Compliance Officer.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

cc:

