



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

12/11/97
732

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-50078

December 11, 1997

Paul H. Codorniz
Codorniz Dairy
17993 Road 96
Tulare, California 93274

WARNING LETTER

Dear Mr. Codorniz:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on November 24 and 25, 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 October 1, 1997, you consigned a dairy cow (identified by USDA laboratory report number 394769) 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 oxytetracycline in the kidney at 0.13 parts per million (ppm), in the liver at

0.15 ppm, and in the muscle at 0.08 ppm. No tolerance level for oxytetracycline has been established for the edible tissues of cattle.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated due to the presence of drug residues. According to USDA analytical reports, during the period of September 5, 1989, to September 28, 1997, your firm delivered [REDACTED] cows and [REDACTED] calf which were found to contain illegal drug residues. An inspection was conducted of your dairy on September 7 and 9, 1994. During the inspection you were warned that it is illegal to market animals with harmful levels of drugs. A warning letter, dated October 25, 1994, 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 failed to take adequate corrective action.

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.

The AmTech Maxim-100 brand of oxytetracycline hydrochloride 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 it is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with its approved labeling. Labeling for Maxim-100 states it is to be administered intravenously to non-lactating dairy cows and calves. Your practice of infusing oxytetracycline hydrochloride into the infected quarters and uterus of your lactating dairy cows 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 comply with the label instructions on Maxim-100 is the likely cause of the presence of the violative level of oxytetracycline residues in the tissues of the animal you sold for food use.

Failure to adhere to the instructions on drugs you use to treat your cows presents the likely possibility that illegal residues will occur and makes the drug 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.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are met. Failure to achieve prompt corrections may result in

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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, California 93707.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

cc:

