



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

D1302 B

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53374

March 31, 1997

Mark A. Cardoza
3052 Van Duzen Street
Fortuna, California 95540-9520

WARNING LETTER

Dear Mr. Cardoza:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on February 27, 1997, by Food and Drug Administration (FDA) Investigator John A. Gonzalez 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 January 23, 1997, you consigned a calf (identified by USDA laboratory report number 391965) 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 sulfamethoxazole at a level of 0.21 parts per million (ppm) in the liver and 0.16 ppm in the muscle. A tolerance level for sulfamethoxazole has not been established for the edible tissues of calves.

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

The tablets containing the drugs Sulfamethoxazole and Trimethoprim that you use to treat your dairy calves are adulterated under Section 501(a)(5) of the Act in that they are new animal drugs within the meaning of Section 201(v), and the tablets are unsafe within the meaning of Section 512(a)(1)(B) since they are not being used in conformance with their approved labeling. Your veterinarian prescribed the tablets containing sulfamethoxazole and trimethoprim for the treatment of scouring in replacement heifers only. Your use of the tablets for treating your bull calves does not conform to prescribed labeling instructions. Failure to adhere to labeling directions for a drug presents the possibility that illegal residues will occur and make the drug 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 at an auction yard where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Cardoza Dairy
Fortuna, California

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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, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to John A. Gonzalez, Investigator, 2202 Monterey Avenue, Suite 104 E, Fresno, California 93721 .

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

cc:

