



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service
Food and Drug Administration

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-52320

October 22, 1998

Heduno V. Brasil, Owner
H & I Dairy
13804 Road 72
Tipton, California 93272

WARNING LETTER

Dear Mr. Brasil:

Tissue residue reports from the United States Department of Agriculture (USDA) and an inspection of your dairy on September 23, 1998, and October 1 through 2, 1998, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon have revealed serious violations of the Federal Food, Drug, and Cosmetic 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 of the Act. On August 21, 1998, you consigned a dairy cow (identified by USDA laboratory report number 208902) to be slaughtered as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of an illegal antibiotic drug residue. USDA analysis of tissues from this animal revealed the presence of streptomycin in the kidney at 3.20 parts per million (ppm). A tolerance level for streptomycin has been established for the kidney tissues of cattle at 2.00 ppm, and 0.5 ppm in other tissues.

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 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.

You are adulterating the drug Quartermaster brand penicillin-dihydrostreptomycin within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) when you do not use this drug in conformance with prescribed labeling. Labeling on the drug requires a withdrawal time of sixty days prior to slaughter and an additional withdrawal time of ninety-six hours after calving. Failure to comply with the withdrawal time is likely the cause of the streptomycin residue in the cow you consigned for slaughter.

You are adulterating the drug Oxy-tet 100 brand oxytetracycline within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with approved labeling. Your practice of mixing 10 mLs of the Oxy-tet 100 brand oxytetracycline with 10 mLs of water to prepare an intrauterine infusion for the treatment of retained placentae in your lactating dairy cattle is an unapproved use for which safety and efficacy have not been proven and constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval. Additionally, labeling directions for Oxy-tet 100 brand oxytetracycline specifically state that it is not to be used to treat lactating dairy cattle.

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Your use of drugs for treating your dairy cows does not conform to the labeling instructions. Failure to comply with the label instructions on drugs used to treat animals makes the drugs unsafe for use.

We request that you take prompt action to ensure that dairy cows and calves 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 into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption 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 animals for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of May 11, 1992, through August 21, 1998, your firm sold five cows which contained violative levels of penicillin, sulfadimethoxine, and streptomycin. During this same period, you sold a calf which was found to be CAST positive by USDA analysis due to the possible presence of violative levels of antibiotics. As a result of the violative residues, inspections were conducted of your dairy on December 20, 1994, and on June 17, 1996. During each of the inspections you were warned that it is illegal to market cull dairy cattle which contain illegal levels of antibiotics. A Warning Letter, dated August 7, 1996, was issued to you as a result of these inspections. Also, the U.S. Department of Agriculture has sent you letters for each of the cull cows and calves in which USDA 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 are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

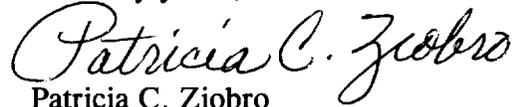
Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should

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include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, Investigator, Food and Drug Administration, 2202 Monterey Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

cc:

