



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M 35691

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

Via Federal Express

Our Reference: 29-53939

March 17, 2000

Robert J. Brouwer, Owner
Harold Brouwer Dairy
1260 South Mariposa Avenue
Visalia, California 93277

WARNING LETTER

Dear Mr. Brouwer:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on February 29 and March 2, 2000, 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)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On January 10, 2000, you consigned a dairy cow (identified by USDA laboratory report number 281438) to be slaughtered for 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 the presence of penicillin in the kidney at 0.27 parts per million (ppm). Presently, the tolerance level for penicillin in the uncooked edible tissues of cattle is 0.05 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 consistent with the directions contained in their labeling.
4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

The drug Microcillin brand of Penicillin G Procaine 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(v), 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. Your veterinarian prescribed Microcillin at a dosage of four milliliters (mLs) per 100 pounds of body weight and warned against releasing animals for slaughter for food use within fifteen days. Labeling for Microcillin also warns against administering more than ten mLs per injection site. Your practice of administering 60 mLs of penicillin G procaine per injection site is likely the cause of the illegal residue found in the animal you sold for food use. Failure to adhere to your veterinarian's prescribed label instructions presents the likely possibility that illegal residues will occur and makes 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 to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

You have failed to take adequate corrective action. 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 our Fresno resident post 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 John A. Gonzalez, Investigator, United States Food and Drug Administration, 2202 Monterey Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,



District Director
San Francisco District

cc:

