



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m304cr

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

Via Federal Express

Our Reference: 29-54538

June 21, 2000

Frank J. Garcia Jr., Partner
Danny Garcia, Partner
Garcia Brothers Dairy
18185 South I Drive
Tulare, California 93274

WARNING LETTER

Dear Messrs. Garcia:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on April 4 through 11, 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 February 4, 2000, you consigned a cow (identified by USDA laboratory report number 281483) 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 an illegal drug residue. USDA analysis of the kidney tissue from this cow revealed penicillin at 0.53 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.

You are adulterating the drug Hanford's US VET brand of penicillin G procaine 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) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling for penicillin G procaine prescribes a dosage of 1 milliliter (mL) per 100 pounds of body weight and warns do not inject more than 10 mLs per site. Your practice of administering a single 20 mL injection into a 1300 pound dairy cow per head per day results in a dosage in excess of that allowed by the labeling. Failure to comply with the label instructions on drugs you use to treat your animals presents the likely possibility that illegal residues will occur and makes the drugs 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.

Your firm has a history of offering cows for sale for human food use which have been found to be adulterated with antibiotic drug residues. According to USDA reports, during the period of March 29, 1999, through February 4, 2000, your firm delivered three cows for food use which were found to contain illegal residues of penicillin and oxytetracycline. An inspection was conducted of your dairy on September 8, 1999. During the inspection you were warned that it is illegal to market animals with illegal levels of antibiotics. A Warning Letter, dated September 24, 1999, was sent to you as a result of the violations found during that inspection.

Garcia Brothers Dairy
Tulare, California

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Also, the US Department of Agriculture sent you a letter for each instance in which their analysis found violative levels of drugs. 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 our Fresno 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 Street, Suite 104 E, Fresno, California 93721.

Sincerely yours,


District Director
San Francisco District

cc:

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