



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Via Federal Express 4165 0456 9808

Our Reference: 29-54538

September 24, 1999

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 September 8 and 10, 1999, 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 July 16, 1999, you consigned a cow (identified by USDA laboratory report number 401765) 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 oxytetracycline in the kidney at 17.00 parts per million (ppm), in the liver at 14.00 ppm, and in the muscle at 5.90 ppm. Presently, the tolerance level for oxytetracycline in the uncooked edible tissues of lactating dairy cattle is zero.

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 are treated 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 consistent with the directions contained in their labeling.
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 AmTech brand of Maxim-100 containing oxytetracycline hydrochloride 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 Maxim-100 specifies the drug is for intravenous administration only and warns against its use in lactating dairy cattle. Your practice of mixing Maxim-100 with sterile water to administer as an intrauterine infusion into your lactating dairy cows is an unapproved use for which safety and efficacy have not been established and which requires the submission of a New Animal Drug Application for FDA approval. It is likely that this practice was the cause of the illegal residue found in the aforementioned cow.

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 not more than 10 ml per injection site. Your practice of administering 2 ml per 100 pounds of body weight per head per day into one injection site 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.

Garcia Brothers Dairy
Tulare, California

3

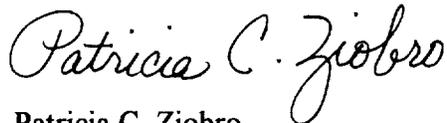
Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

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 being met. Failure to achieve prompt corrections 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,



Patricia C. Ziobro
Director
San Francisco District

cc:

