



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

Our Reference: 2954479

September 7, 2001

Michael T. Parreiro-Pinheiro, Co-owner  
Parreiro-Pinheiro & Sons Dairy  
13881 Road 120  
Tipton, CA 93272

**WARNING LETTER**

Dear Mr. Parreiro-Pinheiro:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a dairy cow that originated from your dairy. As a follow-up to USDA's finding, our investigator performed an inspection of your dairy operation located at 13881 Road 120, Tipton, CA, on August 9 and 10, 2001. The inspection revealed serious violations of Section 402 and 501 of the Federal Food, Drug, and Cosmetic Act (the Act).

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 June 13, 2001, you consigned a dairy cow, identified with back tag number 4231 (USDA laboratory report number 419067), to be sold for human food through [REDACTED]. [REDACTED] USDA analysis of tissue samples collected from that calf identified the presence of the drug penicillin in the liver at 0.35 parts per million (ppm), and in the kidney at 0.86 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. You are not keeping medication records specifying the dosage administered for all drugs and the pre-slaughter withdrawal time.
2. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling or your veterinarian's prescription labeling.
3. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Pfizer Pfi-Pen G 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) of the Act, and is unsafe within the meaning of Section 512 of the Act since it is not being used in accordance with the labeled directions. Pfi-Pen G labeling prescribes a dosage of 1 ml per 100 pounds of body weight with no more than 10 ml administered to any given injection site. Your practice of administering one 35 ml injection per day at one site results in a dosage in excess of that allowed in the labeling. This overdosing presents a possibility that illegal residues will occur and is the likely cause of the illegal residues found in the animal you consigned for slaughter.

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.

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

Parreiro-Pinheiro & Sons Dairy  
Tipton, California

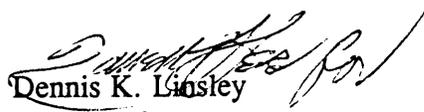
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September 7, 2001

corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify our office in writing, within fifteen (15) working days of the receipt of this letter, 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 Russell A. Campbell, Compliance Officer, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

  
Dennis K. Lusley  
District Director

cc:

[REDACTED]