



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Our Reference: 29-50465

March 26, 1997

Mark L. Pacheco  
6105 Avenue 184  
Tulare, California 93274-9407

WARNING LETTER

Dear Mr. Pacheco:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on February 27 and March 3, 1997, 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)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On January 3, 1997, you consigned a cull dairy cow (identified by USDA laboratory report number 088579) to be slaughtered as human food. This cow, which was delivered for introduction into interstate commerce by your firm, was adulterated by the presence of illegal antibiotic drug residues. USDA analysis of tissues from this animal revealed the presence of sulfadimethoxine in the liver tissue at 7.4 parts per million (ppm) and in the muscle tissue at 6.7 ppm. A tolerance level for sulfadimethoxine has been established for the edible tissue of cattle at 0.10 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.

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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 animals have been treated only 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 not contrary to the directions contained in their labeling.
5. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The Albon brand sulfadimethoxine boluses that you use to treat your dairy cows are adulterated under Section 501(a)(5) of the Act since they are not being used in conformance with approved labeling. Labeling for Albon prescribes 25 grams per pound of body weight followed by 12.5 grams per pound of body weight per day for three to four days. Your practice of using five boluses for one treatment in a twelve to fifteen hundred pound cow is twice the labeled amount allowed. Failure to comply with the labeling instructions is likely the cause of the illegal residue of sulfadimethoxine in the cow you sold for food use.

Your practice of medicating your dairy cows with injectable RXV Oxy-mycin 100 brand oxytetracycline hydrochloride is not in conformance with approved labeling. Labeling for Oxy-Mycin specifically states it is not to be used to treat lactating dairy cattle. The use of oxytetracycline to treat lactating cows will likely cause illegal residues in animals you consign for slaughter.

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.

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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 January 29, 1990, through January 3, 1997, your firm sold eight cows and/or calves which contained violative levels of sulfadimethoxine, oxytetracycline, penicillin, and streptomycin. An inspection was conducted of your dairy on February 28, 1992. During the inspection you were warned that it is illegal to market cull dairy cattle which contain illegal levels of antibiotics. A Warning Letter, dated March 25, 1992, was sent to your firm as a result of the violations found during the inspection. 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 include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, Investigator, Food and Drug Administration, P.O. Box 169, Fresno, California 93707.

Sincerely yours,

*Charles D. Moser, Acting DD*

*PC*  
Patricia C. Ziobro  
District Director  
San Francisco District

Mark L. Pacheco  
Tulare, California

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cc:

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