



San Francisco District  
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**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Our Reference: 29-53274

December 9, 1996

Daniel D. Gouveia  
23561 Turner Avenue  
Hilmar, California 95324

**WARNING LETTER**

Dear Mr. Gouveia:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on October 31 and November 4, 1996, by Food and Drug Administration (FDA) Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (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 August 14, 1996, you consigned a calf (identified by USDA laboratory report number 391595) for sale for slaughter as human food. This calf 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 animal revealed the presence of tetracycline at levels of 25.00 parts per million (ppm) in the kidney, 2.70 ppm in the liver, and 2.30 ppm in the muscle tissues. No tolerance level for tetracycline has been established for the edible tissue of cattle.

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 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 Terramycin TM-50D brand of oxytetracycline hydrochloride that your establishment uses on bull calves is adulterated under Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(w), and it is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with its approved labeling. Your practice of mixing one-half cup of Terramycin into five gallons of fresh milk for use as a medicated milk replacer is not in conformance with approved labeling. Failure to adhere to labeling directions, including recommended withdrawal times, is likely the cause of the illegal residues found in the calf you sold for slaughter. Failure to comply with the label instructions on a drug also makes the drug unsafe.

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 into 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 into 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

Gouveia Dairy  
Hilmar, California

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for sale into 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 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 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 current inspection and in this letter, as well as the inclusion of copies of any available documentation demonstrating that corrections have been made. Your response should be directed to John M. Reves, Compliance Officer.

Sincerely yours,

*Patricia C. Ziobro*

Patricia C. Ziobro  
District Director  
San Francisco District

cc: 