



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

Via Federal Express

Our Reference: 29-54392

April 7, 1999

Augustino R. Dominguez  
5635 Plymouth Avenue  
Corcoran, California 93212

## **WARNING LETTER**

Dear Mr. Dominguez:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your calf raising operation on February 25 and March 9, 1999, by Food and Drug Administration (FDA) Investigator Robert J. Anderson has 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 January 21, 1999, you sold a feeder steer (identified by USDA laboratory report number 815843) which was subsequently slaughtered for human food. This steer 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 steer revealed gentamicin in the kidney at 2.70 parts per million (ppm). Presently, there is no tolerance level for gentamicin in the uncooked edible tissues 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 record keeping system to identify the animals you purchase to establish traceability to the source of the animals.
3. You lack an adequate system to determine from the source of the animal whether the animal has been medicated, and if so, with what drug(s).

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.

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 at an auction yard 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, please notify our Fresno resident post 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 Robert J. Anderson, Investigator, Food and Drug Administration, P.O. Box 169, Fresno, California 93707.

Sincerely yours,

*Charles D. Moss*  
Acting District Director

*for*

Patricia Ziobro  
District Director  
San Francisco District