



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

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

Via Federal Express

Our Reference: 2954856

November 21, 2000

Mr. Frank F. Miranda, Owner
Miranda Livestock
Post Office Box 1407
Hanford, California 93232

WARNING LETTER

Dear Mr. Miranda:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your firm on October 23 and 26, 2000, 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 August 17, 2000, you consigned a calf (identified by USDA laboratory report number 391882) to be slaughtered for 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 calf revealed the presence of sulfamethoxazole in the muscle at 0.43 parts per million (ppm), and in the liver at 0.40 ppm. Presently, there is no tolerance for sulfamethoxazole 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 to this particular residue, "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.

You lack an adequate system for determining the medication status of animals you offer for slaughter. You lack an adequate system for assuring that animals to which medication is administered have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

You are frequently the individual who delivers, or offers for introduction into interstate commerce, calves intended for slaughter for food. As such, you share responsibility for violating the Federal Food, Drug, and Cosmetic Act if such animals are adulterated. To avoid future illegal residue violations, you should take precautions such as:

- 1) implementing a system to identify the animals you purchase with records to establish traceability to the source of the animal;
- 2) implementing a system to determine from the source of the animal whether the animal has been medicated, and if so, with what drug(s); and
- 3) if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If you do not want to hold the medicated animal, then it should be clearly identified and sold to a grower as a medicated animal.

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

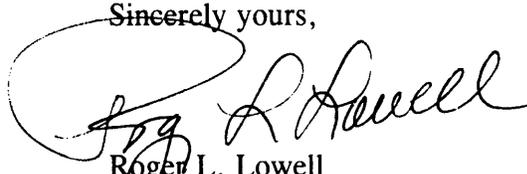
Within fifteen (15) days of the receipt of this letter, please notify our office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state

Miranda Livestock
Hanford, California 93230

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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, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Roger L. Lowell". The signature is written in black ink and is positioned above the printed name.

Roger L. Lowell
Acting District Director
San Francisco District