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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service  
Food and Drug Administration**

**San Francisco District  
1431 Harbor Bay Parkway  
Alameda, California 94102-7070  
Telephone: 510-337-6700**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Our Reference: 29-52337

January 23, 1997

Daniel C. Griffin  
736 North Tommy Road  
Visalia, California 93277

**WARNING LETTER**

Dear Mr. Griffin:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your firm on December 2 and 4, 1996, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the 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 September 9, 1996, you consigned a calf (identified by USDA laboratory report number 391597) 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 streptomycin in the kidney tissue at 4.40 parts per million (ppm). The tolerance level for streptomycin in the edible tissues of calves has been established at 2.00 ppm in the kidney and 0.5 ppm in other tissues.

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, such as streptomycin, 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 clearly be 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 into 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.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated due to the presence of antibiotic drug residues. An inspection was conducted at your firm on July 6 and 11, 1995. During the inspection, you were warned that it is illegal to market cull dairy calves which contain illegal levels of antibiotics in their tissues. A Warning Letter, dated August 17, 1995, was sent to you as a result of the violations found during the inspection. Also, the U.S. Department of Agriculture (USDA) sent you a letter for each instance in which USDA analysis found violative levels of drug residues. You have failed to take adequate corrective action.

Daniel C. Griffin  
Visalia, California

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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, 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 John M. Reves, Compliance Officer.

Sincerely yours,



Patricia C. Ziobro  
District Director  
San Francisco District