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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 94502-7070  
Telephone 510-337-6700

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Our Reference: 29-50240

June 26, 1997

Daniel E. Rocha  
Rocha Dairy  
6551 West Arbor Road  
Tracy, California 95376

**WARNING LETTER**

Dear Mr. Rocha:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on June 11, 1997, by Food and Drug Administration (FDA) Investigator Karen L. Robles 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. On April 1, 1997, you consigned a cow (identified by USDA laboratory report number 384719) for slaughter as human food. This cow 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 cow revealed neomycin in the kidney at 7.50 parts per million (ppm). The tolerance level for neomycin in the uncooked edible tissues of cattle has been established at 00.75 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:

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1. 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.
2. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
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 determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals at your dairy.

You are adulterating the drug [REDACTED] brand neomycin sulfate within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) and unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. Labeling for [REDACTED] specifies for oral use in animals only. Your practice of mixing [REDACTED] with water for intra mammary use is an unapproved use for which safety and efficacy has not been proven. Failure to comply with the label instructions on a drug presents the likely possibility that illegal residues will occur and makes the drug unsafe for use.

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 in 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 in 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 for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

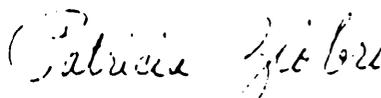
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Based on USDA analytical reports and FDA inspections, your firm has established a history of offering cull dairy cows and/or calves for sale for human food use which have been found to be adulterated with antibiotic drug residues. The U.S. Department of Agriculture has sent you a letter for each instance in which their analysis found the violative levels of antibiotics in your cull dairy cattle. As a result of the USDA analyses, FDA conducted inspections of your dairy on April 30, 1991 and August 1, 1995. During the inspections you were warned that it is illegal to market cull dairy cattle with illegal levels of antibiotics in tissue residues. Warning Letters from the FDA, dated June 27, 1991 and September 1, 1995, were sent to you as a result of the violations found during the inspections. You have failed to take adequate corrective action. 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 our Sacramento 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 Karen L. Robles, Investigator, U.S. Food and Drug Administration, 801 I Street Room 443, Sacramento, California 95814.

Sincerely yours,



Patricia Ziobro  
District Director  
San Francisco District