



**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 94102-7070  
Telephone: 510-337-6700

Via Federal Express

Our Reference 29-54138

February 1, 1999

Frank R. Coelho  
Coelho Dairy  
3130 Dewitt Road  
Modesto, California 95355

**WARNING LETTER**

Dear Mr. Coelho:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your firm on January 6 and 7, 1999, by Food and Drug Administration (FDA) Investigator Karen L. Robles 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 October 1, 1998, you sold a cow (identified by USDA laboratory report number 208932) 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 sulfadimethoxine in the liver at 0.26 parts per million (ppm) and in the kidney at 0.25 ppm. Presently, the tolerance level for sulfadimethoxine is 0.10 ppm in the uncooked edible liver and kidney 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 inadequate and 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 assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
2. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cattle.

You are adulterating the drug Sulfadimethoxine Injection 40% 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 sulfadimethoxine specifies the dosage to be administered in amounts to provide 25 milligrams (mg) per pound for the initial dose, followed by 12.5 mg per pound for maintenance doses every twenty-four hours. The label also requires a five day withholding time prior to slaughter. Your practice of administering 40 to 50 cc's every forty-eight hours in a 1200 to 1400 pound animal presents a possibility that illegal residues will be present in the cows when they are sold for human food use. 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.

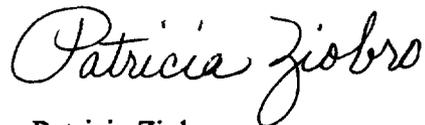
You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Coelho Dairy  
Modesto, CA.

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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,

A handwritten signature in cursive script that reads "Patricia Ziobro". The signature is written in black ink and is positioned above the printed name and title.

Patricia Ziobro  
District Director  
San Francisco District