

M 824 N

4/28/97
2/2/97



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: 29-53368

April 15, 1997

Frank Faria
13182 Robinson Road
Escalon, California 95320

WARNING LETTER

Dear Mr. Faria:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy located at South Temple Creek Road, Escalon, California on February 4 and 7, 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 December 27, 1996, you consigned a cow (identified by USDA laboratory report number 382878) 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 tetracycline in the kidney at 25.00 parts per million (ppm). Presently, the tolerance levels for tetracycline in the uncooked edible tissues of cattle has been established at 2 ppm in the muscle, 6 ppm in the liver, and 12 ppm in fat and kidney 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 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 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 Durvet Duramycin-324 brand tetracycline hydrochloride 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 Duramycin-324 specifies its use in drinking water for swine, calves, and poultry. Your practice of using tetracycline hydrochloride powder mixed with water to create a uterine infusion to medicate your dairy cows is an unapproved use for which safety and efficacy has not been proven. Creating this product constitutes manufacturing a new animal drug which requires the submission of a New Animal Drug Application for FDA approval. 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.

Your firm has a history of offering animals for sale for human food use which have been found to be adulterated with antibiotic drug residues. According to USDA reports, your dairies have delivered other cull dairy cattle which were found by USDA analysis to contain

Frank Faria
Escalon, California

3

violative levels of antibiotics. As a result, an inspection was conducted of your dairy on December 7, 1992. During the inspection you were warned that it is illegal to market cull dairy cattle with illegal levels of antibiotics in tissue residues. A warning letter, dated February 9, 1993, was sent to you as a result of the violations found during the inspection. Also, the U.S. Department of Agriculture sent you a letter for each instance in which their analysis found violative levels of drug residues. 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,

A handwritten signature in black ink, appearing to read "P. Ziobro", followed by a horizontal line.

Patricia Ziobro
District Director
San Francisco District