



DEPARTMENT OF HEALTH & HUMAN SERVICES

7/18/97
v1016 N

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: 29-51059

June 23, 1997

Margaret J. Lourenco
John Lourenco Dairy
2462 Robin Avenue
Livingston, California 95334

WARNING LETTER

Dear Mrs. Lourenco:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on May 13, 1997, by Food and Drug Administration (FDA) Investigator Robert J. Anderson 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 March 10, 1997 you sold a calf (identified by USDA laboratory report number 307824) 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 calf revealed neomycin in the liver at 0.66 parts per million (ppm). The tolerance level for residues of neomycin in the edible tissues of calves has been established at 0.50 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"

Margaret Lourenco
Livingston, California

2

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 determining the medication status of animals you offer for slaughter.
2. 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.
3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

You are adulterating the drugs oxytetracycline hydrochloride and neomycin contained in the product Ellsworth Calf Supplement Medicated within the meaning of Section 501(a)(5) of the Act when you do not use the product in conformance with its approved labeling. Calf Supplement Medicated labeling specifically states that a maximum of 1 oz. is to be used in one gallon of milk, and a thirty day withdrawal time must be instituted when it is used in animals intended for slaughter. Your practice of using two handfuls in five gallons of milk, coupled with a failure to adhere to the required withdrawal time, is not in conformance with approved labeling and is likely the cause of the residues in the calf you sold for food use. Failure to comply with the label instructions on the drugs you use to treat your calves presents the likely possibility that illegal residues will occur and makes the drugs 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

Margaret Lourenco
Livingston, California

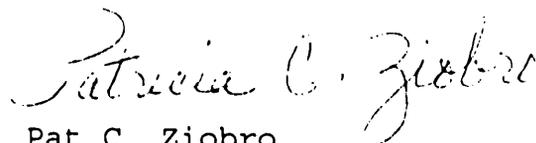
3

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 drug residues. According to a USDA analytical report dated January 23, 1996, your firm offered one other calf which contained violative levels of antibiotics. Also, the U.S. Department of Agriculture sent you a letter covering the first 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 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 Robert J. Anderson, Investigator at P.O. Box 169, Fresno, California 93707.

Sincerely yours,



Pat C. Ziobro
District Director
San Francisco District

cc:

