



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: 29-50979

July 23, 1997

Ernie M. Moules
12406 Clay Station Road
Herald, California 95638

WARNING LETTER

Dear Mr. Moules:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on July 8 and 9, 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 May 16, 1997, you sold a calf (identified by USDA laboratory report number 307846) 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 oxytetracycline in the kidney at 14.00 parts per million (ppm) and in the muscle at 6.70 ppm, as well as penicillin in the kidney at 0.18 ppm and in the liver at 0.16 ppm. Presently, the tolerance levels for oxytetracycline 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 and the tolerance level for residues of penicillin in the edible tissue of cattle has been established at 0.05 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

Moules Dairy
Herald, CA.

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 Ellsworth's brand Calf Energy Formula containing oxytetracycline hydrochloride and 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 Ellsworth's Calf Energy Formula specifies it is for use in reconstituted milk or warm water. Your practice of using Ellsworth's Calf Energy Formula mixed with hospital milk is likely the cause of violative levels of antibiotic residues in the calf you sold for 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.

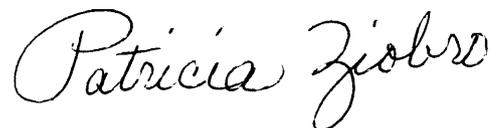
Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

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.

Moules Dairy
Herald, CA.

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".

Patricia Ziobro
District Director
San Francisco District