



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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: 29-52803

May 4, 1998

Mike A. Kuckenbaker
430 West Mount Whitney Avenue
Riverdale, California 93656

WARNING LETTER

Dear Mr. Kuckenbaker:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on April 22, 1998, 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 February 24, 1998, you consigned a dairy cow (identified by USDA laboratory report number 260594 for sale 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 muscle at 12.00 parts per million (ppm), and in the liver at 10.00 ppm. The tolerance level for sulfadimethoxine for the edible tissues of cattle is .10 ppm. Also, neomycin was found in the kidney at 8.50 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" 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 that animals have been treated only with drugs which have been approved for use in their species or class.

The Albon brand of Sulfadimethoxine that you use to treat your dairy cows is adulterated under Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) and is 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 Albon boluses requires a seven day withdrawal period before an animal can be slaughtered for food use. Failure to adhere to the recommended withdrawal time is likely the cause of the presence of violative levels of sulfadimethoxine in the tissues of the animal you sold for food use.

Your use of Tetra-Bac 324 Tetracycline Hydrochloride Soluble Powder 324 is not in conformance with approved labeling. Tetra-Bac 324 labeling prescribes a daily dosage of 10 mg. per pound of body weight for a maximum of fourteen days in calves. Your practice of infusing one or two handfuls of the powder into the uterus of your dairy cows is an unapproved use for which safety and efficacy have not been established.

Your use of the drug Agri-Labs brand of Injectable Penicillin is not in conformance with approved labeling. Agri-Labs Penicillin labeling prescribes a dosage of 1 cc per 100 pounds of body weight per day at no more than 10 cc's per injection site. Your practice of injecting 50 cc's twice per day in a cow all in one site, or infusing 150 cc's in the uterus with 1000 cc's of sterile water for cows with retained placenta, or mixing 4500 cc's of penicillin with one gallon of sterile water for infusion of 16 cc's per quarter in the udders of your dairy cows are all unapproved uses for which safety and efficacy have not been established.

Your use of the drug Anchor Oxy-Tet 100 brand of oxytetracycline is not in conformance with approved labeling. Oxy-Tet 100 labeling specifically states that it is not to be used in lactating dairy cows. Your practice of infusing 60 cc's of this product into the uterus of lactating dairy cows with retained placenta is an unapproved use for which safety and efficacy have not been established.

Your use of the drug AmTech Maxim 100 brand of injectable oxytetracycline is not in conformance with approved labeling. Maxim 100 labeling states that it is not to be used in lactating dairy cows. Your practice of administering 60 cc's intravenously into your cows for treatment of mastitis is an unapproved use for which safety and efficacy have not been established.

Kuckenbaker and Kuckenbaker Dairy
Riverdale, California

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Your use of the drugs you use to medicate your dairy cows is not in conformance with approved labeling directions. Failure to comply with the label instructions on drugs 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.

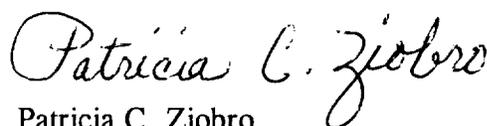
Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

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

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrections now 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, 2202 Monterey Street, Suite 104E, Fresno, California 93721.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

Kuckenbaker and Kuckenbaker Dairy
Riverdale, California

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cc:

