



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53315

December 27, 1996

Michael H. Bottasso
Bottasso Dairy
3151 South Chateau Fresno Avenue
Fresno, California 93706

WARNING LETTER

Dear Mr. Bottasso:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on December 1996, by Food and Drug Administration (FDA) Investigator John A. Gonzalez, have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (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 of the Act. On November 22, 1996, you consigned a cull dairy cow (identified by USDA laboratory report number 382848) for sale for slaughter as human food. This dairy 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 animal revealed the presence of sulfadimethoxine at levels of 3.00 parts per million (ppm) in the liver and 0.83 ppm in the muscle tissues. A tolerance level for sulfadimethoxine has been established at 0.10 ppm in the edible 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 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.
4. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The drug Di-Methox brand of sulfadimethoxine that your establishment uses 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(w), and it is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Sulfadimethoxine labeling warns against releasing dairy cattle for slaughter for food within five days after the last treatment. Failure to adhere to the full withdrawal time is likely the cause of the illegal residues in the cow you sold for food use.

You are using the drug Agri-Cillin brand of penicillin G procaine in a manner not in conformance with its approved labeling directions. Labeling for penicillin G procaine specifies it is to be administered at a dosage of 1 milliliter (ml) per 100 pounds of body weight and warns against using more than 10 mls per injection site. Labeling for this drug requires a four day withdrawal time prior to slaughter. Your practice of administering 25 mls in an animal results in a dosage in excess of that allowed by the labeling.

Failure to adhere to labeling directions, including recommended withdrawal times, and failure to maintain a written record of all drug treatments administered in your dairy animals, presents the possibility that illegal residues will occur and is likely the cause of the illegal residues found in the dairy cow you sold for slaughter. Failure to comply with the label instructions on a drug also makes the drug unsafe.

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.

Michael H. Bottasso
Fresno, California

3

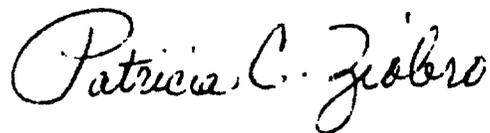
Causing the adulteration of drugs after receipt into interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into 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 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 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 current inspection and in this letter, and should include copies of any available documentation demonstrating that corrections have been made. Please direct your reply to John M. Reves, Compliance Officer.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

cc: 

