



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District *d2008b*
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-51390

August 24, 1998

Ted A. Greidanus, Jr.
CalfTech Corporation
13939 Road 152
Tipton, California 93272

WARNING LETTER

Dear Mr. Greidanus:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your firm on May 28 to August 5, 1998, by Food and Drug Administration (FDA) Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. Our investigation revealed that you administered gentamicin sulfate to calves which were sold on August 21 and 27, 1997. One of these calves (identified by USDA laboratory report number 795744) was sold to be slaughtered for human food use. The calf was delivered for introduction into interstate commerce and was adulterated by the presence of an illegal drug residue. USDA analysis of tissues from this calf revealed the presence of gentamicin at a level of 0.39 parts per million (ppm) in the kidney

tissue. A tolerance level for gentamicin has not been established for 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 to this particular residue, "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. You lack an adequate system for determining the medication status of animals you offer for slaughter. You lack an adequate system for assuring that animals to which medication is administered have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

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.

Your firm has established a history of offering calves for sale for human food use which have been found to be adulterated due to the presence of drug residues. According to USDA analytical reports, during the period of December 29, 1988, to March 26, 1996, nine calves you sold for food use were found to contain violative levels of gentamicin, penicillin, streptomycin, sulfadimethoxine and sulfamethazine. Fifteen other calves your firm delivered for food use were found to be CAST positive due the possilbe presence of harmful levels of antibiotic residues.

You are frequently the individual who introduces, or offers for introduction into interstate commerce, animals intended for slaughter for food. As such, you share responsibility for violating the Federal Food, Drug, and Cosmetic Act if such animals are adulterated. To avoid future illegal residue violations you should take precautions such as:

- 1) implementing a system to identify the animals you purchase with records to establish traceability to the source of the animal;
- 2) implementing a system to determine from the source of the animal whether the animal has been medicated, and if so, with what drug(s); and,
- 3) if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If you do not want to hold the medicated animal, then it should be clearly identified and sold to as a medicated animal.

You are adulterating the drug Fermenta brand of gentamicin 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 it is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with prescribed labeling. Your veterinarian prescribed the gentamicin sulfate for the treatment of pneumonia and diarrhea in your calves, and the labeling warns against releasing calves for slaughter for food use within eighteen months after being medicated. Failure to adhere to an adequate withdrawal time is likely the cause of the illegal residues of gentamicin sulfate found in the calf you sold for food use. Your practice of injecting 2 mLs per 100 pounds of body weight of gentamicin in calves and utilizing a withdrawal time of 125 days will likely result in additional illegal antibiotic residues.

Your use of Spectam, containing the drug spectinomycin, is not in conformance with its approved labeling. Spectam is for use in swine only. Your practice of administering 20 mLs into your calves is an unapproved use for which safety and efficacy have not been established.

Your use of the drug RXV Pen-Aqueous brand of penicillin G procaine is not in conformance with its approved labeling. Pen-Aqueous labeling prescribes a dosage of 1 mL per 100 pounds of body weight and warns against injecting more than 10 mLs per site. Your practice of administering 15 mLs into one site in a calf is an unapproved use for which safety and efficacy have not been established.

Your use of the drug Western Vet Benza-Pen brand of penicillin G Bbnzathine and penicillin G procaine is not in conformance with approved labeling. Benza-Pen labeling prescribes a dosage of 2 mL per 150 pounds of body weight in a subcutaneous manner only in beef cattle. Your practice of administering 15 mLs in an intramuscular manner for respiratory problems and ½ mL under the eyelid for pinkeye are unapproved uses for which safety and efficacy have not been established.

Failure to adhere to your veterinarian's prescribed label instructions and approved labeling directions on drugs you use to treat your animals 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.

CalfTech Corporation
Tipton, California

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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 to a calf dealer who sold the animal to another person who introduced it 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 promulgated thereunder, 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 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 A. Gonzalez, Investigator, 2202 Monterey Street, Suite 104E, Fresno, California 93271.

Sincerely yours,



Patricia C. Ziobro
District Director
San Francisco District

cc:

