



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

D1128B

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-50361

January 27, 1997

Clarence H. Bosman
Bosman Dairy
32960 Road 108
Visalia, California 93291

WARNING LETTER

Dear Mr. Bosman:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on November 15 and 19, 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 September 30, 1996, you consigned a cull dairy cow (identified by USDA laboratory report number 382803) 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 gentamicin at levels of 1.70 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 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 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 assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
5. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The Legacy brand of gentamicin sulfate that your establishment uses on lactating dairy cows is adulterated under Section 501(a)(5) of the Food, Drug, and Cosmetic Act, 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 its approved labeling. Your veterinarian prescribed the gentamicin sulfate for the treatment of scouring in replacement heifers only. Labeling on the drug includes a prescribed withdrawal time of eighteen months prior to slaughter. Failure to adhere to the prescribed withdrawal time is likely the cause of the illegal residues of gentamicin in the cow you sold for human food use.

Your practice of administering a 0.2% solution of the prohibited drug nitrofurazone, a new animal drug under Section 512 of the Act, into lactating dairy cows is in violation of Section 501(a)(5) and Section 402(a)(2)(D). Nitrofurazone has been banned for use in food producing animals since September 4, 1991. Labeling for this drug recommends use in the treatment of topical bacterial infections in dogs, cats, and horses. Our inspection revealed that you are creating a solution by mixing 50 milliliters (mLs) of nitrofurazone, 500 Mls of iodine liquid and one gallon of water. Your practice has been to administer 90 Mls of this solution into the uterus of lactating dairy for removal of the retained placenta. The inspection also revealed that you have used the prohibited solution to treat fifty cows a week for the past one and one-half years.

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Your use of Pen-Aqueous brand of penicillin G procaine is not in conformance with its approved labeling directions. Labeling for Pen-Aqueous prescribes a dosage of 1 MI per 100 pounds of body weight once per day and warns against the administration of more than 10 MIs per injection site. A ten day withdrawal time is required when the drug is used according to its labeling directions. Your firm's administration of this drug as a single 20 MI intramuscular injection into dairy cows weighing 1600 pounds coupled with your administration of 4 MIs into each infected mammary to treat mastitis does not conform to the labeling instructions.

Your use of drugs for treating your dairy cows does not conform to approved labeling instructions. Failure to adhere to the instructions for approved drugs, including withdrawal times and routes of administration, and your practice of administering prohibited drugs, presents the possibility that illegal residues will occur and makes the drugs unsafe to 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 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 into 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 with drug residues. According to USDA analytical reports during the period of April 5, 1996, through November 8, 1996, your firm sold three other dairy cows which contained violative levels of chlortetracycline and penicillin. An inspection of your dairy was conducted on October 4 and 8, 1991. During the inspection, you were warned that it is illegal to market animals containing violative levels of antibiotics in their edible tissues. A Warning Letter, dated November 13, 1991, was sent to you as a result of the violations found during that inspection. Also, the U.S. Department of Agriculture (USDA) sent you a letter for each instance in which USDA 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.

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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 documentation demonstrating that corrections have been made. Your response should be directed to John M. Reves, Compliance Officer.

Sincerely yours,

Charles P. Moss, Acting Director

Per Patricia C. Ziobro
District Director
San Francisco District

cc: [REDACTED]
[REDACTED]
[REDACTED]
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