



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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

Via Federal Express

Our Reference: 29-54407

October 7, 1999

Jason B. Tuls, Partner  
Tuls Cattle Co.  
14998 Avenue 192  
Tulare, CA 93274

**WARNING LETTER**

Dear Mr. Tuls:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your calf raising operations on March 17 and 18, 23 and 24, 1999, by Food and Drug Administration (FDA) Investigator Robert J. Anderson and Thomas W. Gordon have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the 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. On September 24, 1998, you sold a feeder steer (identified by USDA laboratory report number 815843) for slaughter as human food. This steer 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 steer revealed gentamicin in the kidney at 2.70 parts per million (ppm). Presently, there is no tolerance level for gentamicin in the uncooked 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 consistent with the directions contained in their labeling.
4. You lack an adequate system for assuring that animals are treated with drugs which have been approved for use in their class of animal or species.
5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Tamycin 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 is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling for Tamycin states that federal law restricts this drug to use by or on the order of a licensed veterinarian and is for intra-uterine use in horses only. Your practice of administering gentamicin sulfate to calves, coupled with an inadequate withdrawal time, presents a possibility that illegal residues will occur and is likely the cause of the illegal residue found in the calf you sold for food use. In addition, it was noted that the gentamicin sulfate at your firm was not labeled by your veterinarian with adequate directions for use.

You are adulterating the drug Bimeda brand of penicillin G procaine within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling for penicillin G procaine prescribes a dosage of 1 milliliter (ml) per 100 pounds of body weight. Your practice of administering 3 ml per 100 pounds of body weight per head per day in your calves results in a dosage in excess of that allowed by the labeling.

You are adulterating the drug Spectam Scour-Halt brand of spectinomycin within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling for spectinomycin specifically states it is for use in pigs under four weeks of age and prescribes a twenty-one day withdrawal time. Your practice of administering spectinomycin to calves is a use that is not specified according to the label.

Your use of the human drug SoloPak brand of cefazolin sodium U.S.P. was not prescribed and labeled for your use by a licensed veterinarian. Your practice of administering the human drug cefazolin sodium to calves is an unapproved use for which safety and efficacy has not been established and which requires the submission of a New Animal Drug Application for FDA approval.

Our investigation also revealed that you are mixing TM-100 brand of oxytetracycline, Deccox brand of decoquinat, and Neomix Ag 325 brand of neomycin sulfate together with milk to feed your calves aging one to fifteen days. Further, for calves age sixteen to sixty days of age you are using the above mixture and adding the drug Pennchlor 50 brand of chlortetracycline, and occasionally adding the drug Sulforal brand of sulfadimethoxine to this mixture, to feed your calves. You are adulterating these drugs within the meaning of Section 501(a)(6) of the Act, in that the practice of mixing these drugs with milk to feed to your calves are unapproved combinations and they are unsafe within the meaning of 512(a)(2) due to the lack of an approved application and the manufacturing site is not licensed.

Failure to comply with the label instructions 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.

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 are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

Tuls Cattle Co.  
Tulare, California

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Within fifteen (15) days of the receipt of this letter, please notify our Fresno 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 United States Food and Drug Administration, Robert J. Anderson, Investigator, 2202 Monterey Street, Suite 104E, Fresno, California 93721.

Sincerely yours,



Patricia C. Ziobro  
Director  
San Francisco District

cc:

