



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M2840N

August 4, 1999

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

Ref: 99-DAL-WL-25

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Skeeter R. Ferguson, Owner
Ferguson Cattle Co.
443 CR 481
Stephenville, TX 76401

Dear Mr. Ferguson:

An investigation of your cattle producer/dealer operation on May 14 and 18, 1999, confirmed that you repeatedly offer animals for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). A food is adulterated if it bears or contains a new animal drug (or conversion product thereof) which is unsafe within the meaning of Section 512 of the Act [Section 402(a)(2)(C)(ii)].

On or about January 12, 1999, you delivered a bob veal calf identified with back tag #1389 for slaughter as human food at ABF Packing, Inc., #3 Beyer Center, Dublin, TX. USDA analysis (Laboratory Report #817014) of tissue samples collected from this animal identified the presence of streptomycin at 2.10 ppm in kidney. A tolerance of 2.0 ppm has been established for residues of streptomycin in the kidney of calves. (Title 21 Code of Federal Regulations, Section 556.610). USDA analysis also confirmed the presence of sulfamethoxazole in the edible tissue of this animal. A tolerance has not been established for sulfamethoxazole in calves, therefore, the presence of this drug and streptomycin, exceeding the established tolerance level, causes the food to be adulterated.

Additionally, on or about January 25, 1999, you delivered a holstein cow identified with back tag #1796, for slaughter as human food at ABF Packing, Inc. USDA analysis (Laboratory Report #352653) of tissue samples collected from this animal identified the presence of oxytetracycline at 10.00 ppm in liver, 110.00 ppm in kidney, and 11.00 ppm in muscle. Tolerances for oxytetracycline residues in edible tissues of cattle and dairy animals have been established as follows: 6 ppm in liver, 12 ppm in kidney, and 2 ppm in muscle. (Title 21 Code of Federal Regulations, Section 556.500). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

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Furthermore, you offered a veal calf for slaughter for food at ABF Packing, Inc. on or about January 14, 1999, for which USDA reported a streptomycin residue of 2.30 ppm in kidney tissue. The Food and Drug Administration is also aware of USDA tissue residue reports of violative levels of oxytetracycline and gentamycin reported on or about July 9 and 14, 1998 in veal calves you offered for slaughter at ABF Packing, Inc. A follow-up inspection by the Texas Department of Health on September 15, 1998, confirmed that you had no medication records for animals treated at your facility, and you had no system of identifying the source of animals purchased at auction markets and subsequently offered for slaughter as food. I have attached copies of USDA's history of Residue Violation Data on your firm and letters addressed as a result of the violations.

A food is also adulterated if it has been held under insanitary conditions whereby it may have been rendered injurious to health [Section 402(a)(4) of the Act]. 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.

Our investigation found that as a dealer of animals for slaughter you purchase animals from auction facilities, which you typically hold at your firm for 1 to 6 days prior to offering the animals for slaughter. Your practice is to remove identification tags from these animals, and you make no effort to determine the source of the animals for traceback purposes. You have no assurance, and make no attempt to gain the assurances from the producers or auction markets that the animals purchased by your operation and offered for slaughter have not been medicated prior to your shipment of the animals to the slaughter facility.

Our investigator also determined that you routinely make it a practice to medicate your animals with more drug product than drug labeling directs. You explained the reason is because you believe the labeled dosage for drugs is not sufficient to help a sick animal. Such a practice is considered extralabel use of drugs and may result in additional violative drug residues. Your use of drugs in this manner causes the drugs to become adulterated and unsafe under the Act, because labeled drug withdrawal statements are established based on strict adherence to drug manufacturer's labeled dosage instructions.

For your information, the extralabel use of veterinary drugs is only authorized by or under the direction of a licensed veterinarian having a valid veterinarian-client-patient relationship and assuming the responsibility for making such medical judgements regarding the health of the animal(s).

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As a producer and dealer of animals, which are offered for use as food, you are responsible for assuring that your overall operation and the food you distribute are in compliance with the law. As a dealer of animals you are frequently the individual who introduces or offers for slaughter into interstate commerce the adulterated animal, as such you share responsibility for violating the Act. 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 with what drugs; and
- 3) If the animal has been medicated, implementing a control system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues.

The above is not intended to be an all-inclusive list of violations. You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to James R. Lahar, Compliance Officer, at the above letterhead address.

Sincerely yours,

Sore

Joseph R. Baca
District Director