



June 14, 2001

Via Federal Express

J. Kenneth Fussell
2221 Abiff Road
Burns, TN 37029-5419

Warning Letter No. 01-NSV-32

Dear Mr. Fussell:

An investigation at your beef cattle farm located at Burns, Tennessee, conducted by our investigator on April 26, 2001 confirmed that you offered a cow 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), and that you may have caused an animal drug to become adulterated within the meaning of Section 501(a)(5).

On or about February 26, 2001, you sold a cow, identified by U.S. Department of Agriculture (USDA) sample number 226041 and back tag number 63FS0954, for slaughter as human food at [REDACTED]. USDA analysis of tissue samples collected from that cow identified the presence of 2.63 parts per million (PPM) of penicillin in the kidney tissue. A tolerance of 0.05 PPM has been established for penicillin in the edible tissue of cattle (Title 21, Code of Federal Regulations, Part 556.510). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling, and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

You are adulterating the drug Pfizer Pen BP-48, Sterile Penicillin G Benzathine and Penicillin G Procaine in aqueous suspension, that your firm uses on beef cattle, within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the penicillin in cattle in higher than labeled dosages and without following labeled withdrawal period causes the drug to be unsafe to use.

This letter may not list all the deviations at your firm. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing within fifteen (15) working days of the steps that you have taken to bring your farm into compliance with the law. Your response should include each step taken to correct the violations and prevent their recurrence. If you cannot complete all corrections within 15 working days, we expect you to explain the reason for your delay and state when any remaining deviations will be corrected. Please include copies of any documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Karen Gale Sego, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,



Carl E. Draper
Director, New Orleans District