



DEPARTMENT OF HEALTH AND HUMAN SERVICES

93330
Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127
JAN

June 7, 2002

VIA FEDERAL EXPRESS – NEXT DAY

Mr. Bill Lawson
Bill Lawson Livestock
230 Frank Thacker Lane
Greeneville, TN 37745-2758

Warning Letter No. 02-NSV-29

Dear Mr. Lawson:

An inspection of your operation located in Greeneville, Tennessee, was conducted by our investigator on April 23, 2002. That inspection confirmed that you offered a calf 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 and medicated feed to become adulterated within the meaning of Sections 501(a)(5) and (a)(6), respectively. You can find this Act and associated regulations through links on FDA's home page at www.fda.gov.

On or about January 14, 2002, you sold a calf, identified by U.S. Department of Agriculture (USDA) sample number 421180 and back tag number 23GR3411, to [REDACTED] which was slaughtered for human food at [REDACTED]. USDA analysis of tissue samples collected from the calf identified the presence of 1.47 parts per million (ppm) neomycin in kidney tissue and 0.12 ppm and 27.33 ppm sulfamethazine in liver and muscle tissue, respectively. There are no established tolerances for neomycin and sulfamethazine in calves (Title 21, Code of Federal Regulations (21 CFR) 556.430 and 556.670). The presence of these drugs in the edible tissue from this animal causes the food to be adulterated.

Our investigator also found that you hold animals under conditions which are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated only with drugs and medicated feeds which have been approved for use in those animal species and for assuring that drugs and medicated feeds are used in a manner not contrary to the directions contained in the labeling. Foods from animals held under such conditions are adulterated.

You are adulterating within the meaning of Section 501(a)(5) the drug Sulmet, a brand of sulfamethazine, when you fail to use the drug in conformance with the approved labeling. Your use of the drug in calves under one (1) month old causes the drug to be unsafe and, therefore, adulterated.

You are also adulterating within the meaning of Section 501(a)(6) the medicated feed Nurse Chow #100 NEO-OTC, which contains neomycin, when you fail to use the feed in conformance with its approved labeling. Your use of this feed in calves to be processed for veal is an unapproved use that causes the medicated feed to be unsafe and, therefore, adulterated.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

The violations listed above are not intended to be an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law. As a dealer/hauler of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce the adulterated animal. 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;
3. implementing a system to assure that the animal species is medicated according to approved label use;
4. 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 not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your operation into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,


Carl E. Draper
Director, New Orleans District

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