



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94014d

Food and Drug Administration  
New Orleans District  
Nashville Branch Office  
297 Plus Park Blvd.  
Nashville, TN 37217

May 12, 2003

**VIA FEDERAL EXPRESS**  
**OVERNIGHT DELIVERY**

Mr. David Hudson  
91 Flintville School Road  
Flintville, TN 37335-5133

Warning Letter No. 03-NSV-15

Dear Mr. Hudson:

On March 7, 2003, the United States Food and Drug Administration conducted an inspection of your dairy farm located in Flintville, Tennessee. That inspection 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) of the Act. You can find this Act and associated regulations through links on FDA's home page at [www.fda.gov](http://www.fda.gov).

On or about January 21, 2003, you sold a cow identified by U.S. Department of Agriculture (USDA) sample number 227490 and back tag number 63LL0302 to [REDACTED], which was then slaughtered for human food at [REDACTED]. USDA analysis of tissue samples collected from the cow identified the presence of 4.37 parts per million (ppm) and 8.17ppm sulfadimethoxine in liver and muscle tissue, respectively. A tolerance of 0.1ppm has been established for residues of sulfadimethoxine in edible tissue of cattle under Title 21, Code of Federal Regulations (CFR) Section 556.640. The presence of this drug in the edible tissues from this animal cause the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigator also found that you hold animals under conditions which are so inadequate that medicated animals having potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residue of drugs from edible tissue. Food from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

Additionally, failure to use a drug in conformance with its approved labeling renders it unsafe within the meaning of Section 512(a)(1) and adulterated within the meaning of Section 501(a)(5) of the Act. The presence of illegal residues of the drug sulfadimethoxine in the cow that you sold establishes that drug was not used in conformance with its approved labeling. Therefore, your

use of the drug in a cow without following the labeled withdrawal period causes the drug to be unsafe and adulterated within the meaning of Section 501(a)(5) of the Act.

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

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the 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.

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.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the steps 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 corrections within 15 working days, we expect you to explain the reason for the delay and state when any remaining deviations will be corrected. Please include copies of any 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, Tennessee 37217.

Sincerely,



Howard E. Lewis  
Acting Director, New Orleans District

JEH:ss

Enclosure:  
21 CFR 556.640