



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

Telephone: 615-781-5380
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April 7, 2004

Warning Letter No. 2004-NOL-20

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Frank Kilpatrick
2625 Ownby Road
Lewisburg, Tennessee 37091

Dear Mr. Kilpatrick:

An inspection of your operation located in Lewisburg, Tennessee, was conducted by our investigator on January 14 and 21, 2004. That inspection confirmed that you offered a dairy cow for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii) and 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and associated regulations through links on FDA's homepage at www.fda.gov.

On October 23, 2003, you sold a Holstein dairy cow; identified by U.S. Department of Agriculture (USDA) sample number 423394 and back tag number 1969, to [REDACTED], which was slaughtered for human food at [REDACTED]. USDA analysis of tissue samples collected from the cow identified the presence of 0.46 parts per million (ppm) gentamicin in kidney tissue. There is no tolerance established for residues of gentamicin in edible tissues of cattle (Title 21, *Code of Federal Regulations*, Part 556.300). The presence of this drug 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 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 animals have been treated only with drugs which have been approved for use in those species; 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.

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 producer of animals offered for

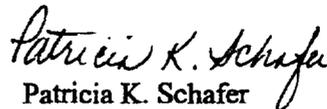
use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct 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.

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 fifteen (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 Kari L. Batey, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483