



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

g1712d

August 31, 2001

VIA FEDERAL EXPRESS

WARNING LETTER
(01-ATL-76)

Hugh C. Cox, Owner
Hugh Cox Livestock
762 Boone Farm Road
Calhoun, Georgia 30701

Dear Mr. Cox:

An inspection of your operation was completed by Food and Drug Administration Investigator Myla D. Chapman on June 22, 2001. Her inspection confirmed that dairy cattle purchased and sold by you on four occasions contained violative drug residues. These cattle were sold for slaughter for human food to [REDACTED] in [REDACTED]. These drug residues caused the food to be adulterated under Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about February 05, 2001, you sold a dairy cow to [REDACTED] identified as USDA laboratory report number 226050. The United States Department of Agriculture (USDA)/Food Safety and Inspection Service (FSIS) analysis of tissue collected from that animal disclosed the presence of the drug penicillin at levels of .96 parts per million (ppm) in the kidney tissue. The allowable tolerance established for residues of penicillin in the edible tissues of cattle (Title 21, Code of Federal Regulations (21 CFR), Section 556.510) is .05 ppm.

On or about December 5, 2000, you sold a dairy cow to [REDACTED] identified as USDA laboratory report number 226038. USDA/FSIS analysis of tissue collected from that animal disclosed the presence of the drug penicillin at violative levels of .1 ppm in the kidney tissue.

On or about November 30, 2000, you sold a dairy cow to [REDACTED] identified as USDA laboratory number 226035. USDA/FSIS analysis of tissue collected from that animal disclosed the presence of the drug penicillin at violative levels of .31 ppm in the liver and 1.43 ppm in the kidney tissue.

On or about August 28, 2000, you sold a dairy cow to [REDACTED] identified as USDA laboratory number 408436. USDA/FSIS analysis of tissue collected from that animal disclosed the presence of the drug sulfadimethoxine at levels of 1.17 ppm in the liver and 3.6 ppm in the muscle tissue. A tolerance of .1 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle (21 CFR 556.640).

The presence of the above drugs at the reported levels in edible tissue from the animals tested cause the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act. USDA has reported these findings of illegal residues in cattle sold by you and offered for slaughter for human food. Copies of the letters from USDA/FSIS notifying you of these residues are enclosed.

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 being initiated by the FDA 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 of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Federal Food, Drug and Cosmetic 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 drug(s); and
3. if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to delete potentially hazardous residues of drugs from edible tissue. 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 be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

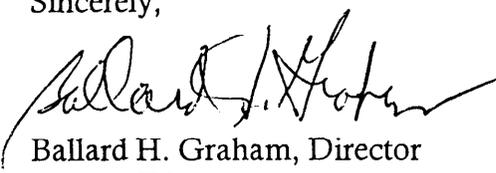
Of additional concern is the fact that you were made aware of your responsibilities in a Warning Letter that issued to you in November 1996. This letter was issued in response to violative residues found in another animal that you had sold for slaughter for human consumption. This inspection again found that you make no effort to obtain assurances from the sources you purchase from that the animals have not been medicated and are free

from drug residues. You and your agents should be determining the medication status of the animals you purchase from dairy farms, auction houses and private individuals.

You should notify this office in writing within fifteen (15) working days of the steps you have taken to bring your firm 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 Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a long horizontal stroke at the end.

Ballard H. Graham, Director
Atlanta District

Enclosures