



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

94784d

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

May 10, 2004

VIA FEDERAL EXPRESS

WARNING LETTER
(04-ATL-9)

John Eaker, Co-Owner
Rusty Eaker, Co-Owner
Eaker Dairy
601 Roy Eaker Road
Cherryville, North Carolina 28021

Dear Mr. Eaker:

An investigation of your dairy farm operation by Investigator Richard L. Garcia on March 16 & 17, 2004, confirmed that you offered animals for sale for slaughter as food, in violation of the Federal Food, Drug, and Cosmetic Act (the Act). The animals were adulterated food within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Act. In addition, you were responsible for causing an animal drug product to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about October 10, 2003, you sold a cow, identified with tag # [REDACTED] to [REDACTED] in [REDACTED]. This cow was sold for slaughter as human food. The United States Department of Agriculture (USDA)/Food Safety and Inspection Service (FSIS) analysis of tissue collected from that animal (Case No. 8-0850-03) disclosed the presence of 0.15 parts per million (ppm) of penicillin in the liver tissue.

On or about July 31, 2003, you also sold a cow, identified with tag # [REDACTED], to [REDACTED] which was also sold for slaughter as human food. USDA/FSIS analysis of tissue collected from that animal disclosed the presence of 0.12 ppm of penicillin in the kidney tissue.

The tolerance established for residues of penicillin in the liver and kidney tissue of cattle is 0.05 ppm. The tolerances for penicillin are listed in Title 21, Code of Federal Regulations, Part 556.510 (copy enclosed). The presence of this drug at levels above the established tolerance in the edible issues of animals causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions whereby 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 which have been treated are withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from their edible tissues. You failed to assure that drugs are not used in a manner contrary to the directions contained in the labeling. Our investigator found that you failed to maintain animal medication records that would identify which animal had been medicated, what type of medication had been used, the treatment date, the dosage administered, the route of administration, and the necessary withdrawal times. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

In addition, you caused the adulteration of the penicillin drug used, within the meaning of Section 501(a)(5) of the Act, when you administered it to cattle in the manner you described to our investigator. Our investigator was told that the drug had not been prescribed by a veterinarian. A drug is adulterated when it is not used in accordance with its labeled instructions, or, if used in an extra-label manner, in accordance with a lawful order of a licensed veterinarian that is in compliance with the extra-label use regulations at 21 CFR Part 530. Use of the drug contrary to its labeled instructions, resulting in a residue which may present a risk to public health and which is above an established tolerance, causes the drug to be unsafe within the meaning of Section 512 of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

The above-identified violations are not intended to be an all-inclusive list of deficiencies at your dairy farm. The FDA investigator issued a list of Inspectional Observations (Form FDA 483) to John Eaker at the conclusion of the inspection. 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.

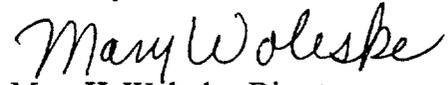
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in enforcement action being initiated by the FDA without further notice, such as seizure and/or injunction.

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 caused the adulteration of an animal that is 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 receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely,

A handwritten signature in cursive script that reads "Mary Woleske".

Mary H. Woleske, Director
Atlanta District

Enclosure