



DEPARTMENT OF HEALTH & HUMAN SERVICES

m38301

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, New York 14202

June 9, 2000

WARNING LETTER NYK 2000-77

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Cedric M. Barnes, Jr., Part Owner
Gate House Farms
279 E. Lake Road
De Ruyter, New York 13052-9518

Dear Mr. Barnes:

On March 1, 2 and 27, 2000, a U.S. Food and Drug Administration investigator conducted an inspection at your dairy operation located in De Ruyter, New York. This inspection confirmed that in March 1999 and May 1999 you offered two animals for sale for food in violation of Sections 402 (a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about March 3, 1999, you offered a cow identified with back tag 252 for slaughter as human food. The cow was slaughtered on March 5, 1999 [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of 0.36 parts per million (ppm) penicillin. A tolerance of 0.05 ppm has been established for residues of penicillin in edible tissues of cattle (Title 21 Code of Federal Regulations 556.510). The presence of this drug in kidney tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about May 24, 1999, you offered a cow identified with ear tag R114 for slaughter as human food. The cow was later slaughtered [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of 8.1 parts per million (ppm) gentamicin. There is no permitted level for residues of gentamicin in edible tissues of cattle. The presence of this drug in kidney tissue of this animal 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 on your farm under conditions that 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; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

You also caused the drugs [REDACTED], containing gentamicin sulfate and dexamethasone, and [REDACTED], containing penicillin, to become adulterated within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with their labeling. Your use of these drugs without following the labeled withdrawal periods causes the drugs to be unsafe for use.

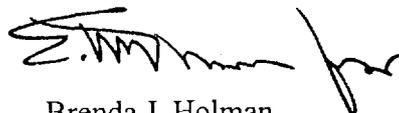
You should not consider this to be an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action, without further notice. This may include seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact you caused the adulteration of an animal sold and subsequently offered for sale to a slaughterhouse which ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. Your response should be directed to Lisa M. Utz, Compliance Officer, at the above address.

Sincerely,



Brenda J. Holman
District Director