



DEPARTMENT OF HEALTH & HUMAN SERVICES

11/25/99
New York District

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

March 17, 2000

WARNING LETTER NYK 2000-44

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Donald C. Cook, Owner
Donnivale Farm
247 County Road 20
Sherburne, New York 13460

Dear Mr. Cook:

An investigation at your dairy operation located at Sherburne, New York conducted by our investigator on January 27, 2000 confirmed that in October 1999 you offered an animal for sale for slaughter as food in violation of Sections 402 (a)(2)(C)(ii) of the Federal Food, Drug and Cosmetic Act (the Act). The inspection also revealed that you caused an animal drug to become adulterated within the meaning of Section 501(a)(5).

On or about October 13, 1999, you offered a cow identified with ear tag 21WZW2784 for slaughter as human food. The cow was slaughtered on October 14, 1999 at [REDACTED], [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of 2.90 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.

You caused the drug [REDACTED] containing gentamicin sulfate, to become adulterated within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its labeling. Your use of the drug without following the labeled withdrawal period causes the drug 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.

Donnivale Farm
Page 2

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

cc: Tri-County Veterinary Medicine, LLC
5033 State Hwy. 8
New Berlin, New York 13411

cc: David A. Unger
RR #1
Box 10 Smith Rd.
Hamilton, New York 13346