



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

m3530n

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

March 8, 2000

WARNING LETTER NYK 2000-45

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John E. Schell
Box 137 F, Cranston Road
Earlville, New York 13332

Dear Mr. Schell:

An investigation at your dairy operation located at Earlville, New York conducted by our investigator on February 1 and 2, 2000 confirmed that in March 1999 you offered an animal 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 an animal drug to become adulterated within the meaning of Section 501(a)(5).

On or about March 8, 1999, you offered a cow identified with ear tag 21WWD9524 for slaughter as human food. The cow was slaughtered on March 11, 1999 at [REDACTED]. [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of 2.70 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 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 this drug without following the labeled withdrawal period causes the drug to be unsafe for use.

John E. Schell
Page 2

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

cc: [REDACTED]

cc: [REDACTED]