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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

November 10, 1999

WARNING LETTER NYK 2000-09

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Craig R. Phelps, Co-Owner
Edgewood Farms
5064 Wilson Road
Groveland, NY 14462

Dear Mr. Phelps:

An investigation performed by U.S. Food and Drug Administration Investigator William P. Chilton included an inspection of your dairy farm on June 1-2 & 4, 1999. The inspection/investigation confirmed that in April 1998, and again in March 1999, you offered an animal for sale for food in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). Both animals were subsequently found by USDA to contain illegal drug residues in tissue samples collected at the time of slaughter. In addition, the inspection found that animal drugs at your farm were used contrary to label instructions, and treated animals were not withheld from slaughter for the time periods specified in the drug labeling. Such usage caused the animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about 3/31/99 you sold a cow bearing barn tag 1295 and ear tag 23VXS2648 to [REDACTED] for slaughter for human food. The cow was slaughtered at [REDACTED] on 4/1/99. USDA analysis of samples collected from that animal identified the presence of 3.70 PPM oxytetracycline in muscle tissue. This exceeds the 2 PPM tolerance identified in 21 CFR 556.200 for muscle tissue of *nonlactating* dairy cattle. It also exceeds the 2 PPM tolerance approved in July 1998 for oxytetracycline in muscle tissue of *lactating* dairy cows (NADA 113-232, Pfizer's LA-200). The presence of oxytetracycline at this level in kidney tissue causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about 4/27/98, you sold a cow bearing barn tag 449 and ear tag 21WZF2748 to [REDACTED] for slaughter for human food. The cow was slaughtered on 4/28/98 at [REDACTED]. USDA analysis revealed the presence of 0.57 PPM gentamycin in kidney tissue collected from that animal. There is no permitted level for residues of gentamycin 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 inspection/investigation did not identify the specific drug treatment that resulted in the two aforementioned residues. However, it did confirm that gentamycin-containing drug products were in use at your farm in April 1998 when you sold the cow in which the gentamycin residue was found. It also confirmed that oxytetracycline-containing drug products were in use at your farm in March 1999 when you sold the cow in which the illegal oxytetracycline residue was found. The inspection did confirm that animals on your farm are held under conditions which are so inadequate that animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring drugs are used in a manner not contrary to label instructions, and for assuring animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

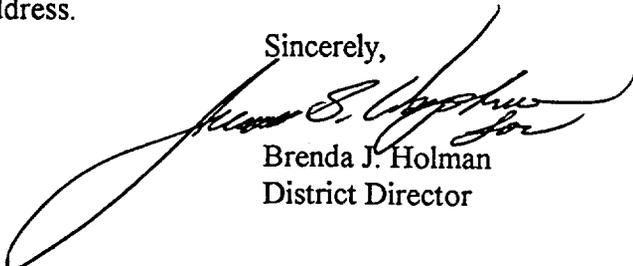
The inspection also found the drug products *Pirsue Aqueous Gel* (Pharmacia & Upjohn brand of pirlimycin hydrochloride); *STATUS SQ* (Boehringer Ingelheim brand of oxytetracycline HCl injection); and *Banamine Injectable Solution* (Schering-Plough brand of flunixin meglumine) used on your farm became adulterated within the meaning of Section 501(a)(5) of the Act. They become adulterated when they were used contrary to their labeled instructions. A cow on your farm was treated with *Pirsue* in excess of the labeled dosage, and was not withheld from slaughter for the 28 day period specified in the product labeling. That cow was also treated intravenously with *Status SQ*, and was not withheld from slaughter for the 13 day period specified in the product labeling. Another cow (lactating) was treated with *Banamine* contrary to label instructions and was not withheld from slaughter for the 4 day period specified in the product labeling. Use of these drugs contrary to label instructions, without following the specified withdrawal periods, causes them to be unsafe for use.

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 that you caused the adulteration of an animal that was 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 15 working days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address.

Sincerely,



Brenda J. Holman
District Director