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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

April 19, 2004

WARNING LETTER NYK 2004-13

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Lyn F. Main, Owner
Berkshire Valley Holsteins
N. Mountain Road, PO Box 27
Copake, New York 12516

Dear Mr. Main:

An investigation performed by U.S. Food and Drug Administration Investigator Michael G. Sinkevich included an inspection of your dairy farm on February 9-10, 2004. The investigation confirmed you offered a cow and a calf for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In addition, your extra label usage, and the illegal tissue residue that resulted, caused the drug product [REDACTED] PEN-AQUEOUS to become adulterated within the meaning of Section 501(a)(5) of the Act.

On September 20, 2003, a dairy cow bearing farm tag 1119 was administered an injection of PEN-AQUEOUS Penicillin G Procaine at your farm. The cow was subsequently shipped from your farm on September 29, 2003 and offered for sale for human food through [REDACTED]. USDA analysis of samples collected from that animal on September 30, 2003 at [REDACTED] identified the presence of 00.12 parts per million (ppm) penicillin in kidney tissue.

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 penicillin at the reported level in the edible 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 December 2, 2002 a bob veal calf identified with tag number A490 was shipped from your farm and offered for sale for human consumption through [REDACTED]. USDA analysis of samples collected from that animal on December 3, 2002 at [REDACTED] identified the presence of 08.02 ppm neomycin in kidney tissue.

No tolerance has been established for residues of neomycin in any edible tissue of bob veal calves. The presence of neomycin in the kidney tissue of this calf causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found you hold animals under conditions whereby medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling, and for assuring that

animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. For example, you lack adequate written treatment records for veterinary drugs administered to your herd. Such records would identify the drugs administered, the treatment date, identification of the animal treated, the dosage administered, the route of administration, the individual administering the medication, and the withdrawal times for milk and beef. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

In addition, you are adulterating the veterinary drug [REDACTED] PEN-AQUEOUS penicillin G procaine within the meaning of Section 501(a) (5) of the Act, when you fail to use it in accordance with its labeled instructions. The drug label specifies that its use must be discontinued for 10 days before treated animals are slaughtered for food. The failure to comply with this withholding requirement prior to your September 29, 2003 shipment of cow 1119 for sale for human food caused the drug to be unsafe within the meaning of Section 512 of the Act. All drug labels need to be carefully followed including the class of animal the drug will be administered to.

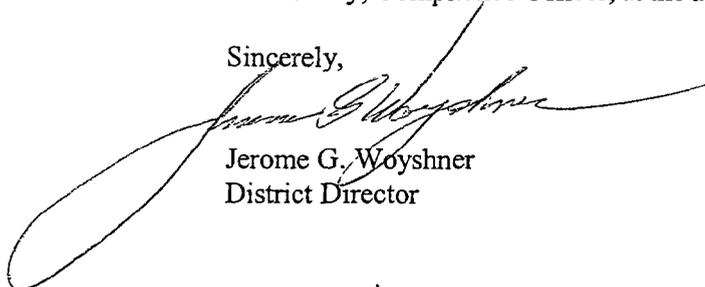
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include seizure or injunction.

This letter is not intended to be an all-inclusive list of violations. 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.

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 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,



Jerome G. Woyshner
District Director