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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David J. Boor, Owner
Boor Crest Farm
118 Middle Road
Horseheads, NY 14845-9333

May 13, 2004

Ref: NYK-2004-15

Dear Mr. Boor:

An inspection at your dairy farm located in Horseheads, New York, conducted by a Food and Drug Administration investigator on February 18 and 27, 2004, confirmed that you offered for sale animals for slaughter as food that were adulterated within the meaning 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 be unsafe under Section 512(a) of the Act, and adulterated within the meaning of Section 501(a)(5) of the Act, because the drugs were used in a manner that did not conform to their approved use or to the regulations for Extralabel Drug Use in Animals (Title 21, *Code of Federal Regulations* ("CFR"), Part 530).

On or about November 10, 2003, you sold a bob veal calf (identified by U.S. Department of Agriculture ("USDA") Sample No. 435009 and back tag no. [REDACTED]) for slaughter for human food through [REDACTED] located in [REDACTED] USDA's Food Safety and Inspection Service ("FSIS") analysis of tissue samples collected from that animal found 13.51 ppm of the drug neomycin in kidney tissue. There is no established tolerance for residues of neomycin in the edible tissues of calves (21 CFR 556.430). The presence of this drug at the reported level in edible tissue from 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 under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues; and for assuring the proper accounting of all drug products used on your animals. You also failed to maintain any treatment records for your calves and adequate treatment records for your cows. Food from

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animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

Neomycin is not approved for use in veal calves. However, the extralabel use of approved veterinary or human drugs is allowed if the use complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 CFR Part 530. Our investigation found that your extralabel use of neomycin failed to comply with these requirements. For example, you administered neomycin to calf number 1505 without the supervision of a licensed veterinarian, in violation of 21 CFR 530.11(a), and your extralabel use resulted in an illegal drug residue, in violation of 21 CFR 530.11(c). Because your extralabel use of neomycin was not in compliance with 21 CFR 530, the drug was unsafe under Section 512(a) of the Act and your use caused it to be adulterated within the meaning of Section 501(a)(5) of the Act.

We note that this is not the first residue associated with your farm. Our investigation found that on or about April 14, 2003, you sold a cow (identified by USDA Sample No. 432807, back tag no. "23TP2728" and sale tag no. "410" (your barn no. "121")) for slaughter for human food through [REDACTED] located in [REDACTED]. FSIS analysis of tissue samples collected from that animal found 0.12 ppm of the drug penicillin in kidney tissue. The tolerance for residues of penicillin (21 CFR 556.510) is 0.05 ppm in the edible tissues of cattle.

You should not consider this letter to be an all-inclusive list of violations existing at your farm. 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.

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

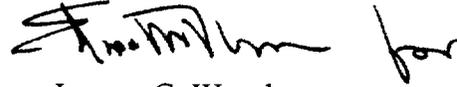
It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act. Likewise, the fact that you caused the adulteration of a drug that had been sold 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 farm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

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Your reply should be sent to the Food and Drug Administration, Attention: Bruce A. Goldwitz, Compliance Officer, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions regarding this letter, you can contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner". The signature is stylized and includes a large, sweeping flourish at the end.

Jerome G. Woyshner
District Director