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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**

Mr. Thomas O. Leduc, Co-owner
Green Acre Farm
562 Leggett Rd.
Champlain, NY 12919

August 13, 2003

File No.: NYK 2003-32

Dear Mr. Leduc:

On April 30, May 22, and June 2, 2003, U.S. Food and Drug Administration investigators conducted an inspection at your farm located in Champlain, New York. This inspection confirmed that in September 2002, you offered an animal for sale for food that was 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 an animal drug 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 drug was used in a manner that does not conform to its approved use or the regulations for Extralabel Drug Use in Animals (Title 21, Code of Federal Regulations, Part 530).

On or about September 3, 2002, you offered for sale a cow identified with yellow ear tag 1701 for slaughter as human food. The cow was sold to and slaughtered at [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of 5.20 parts per million (ppm) and 3.39 ppm sulfadimethoxine in liver and muscle tissues, respectively.

A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in edible tissues of cattle (21 CFR 556.640). The presence of this drug in excess of the established tolerance in the liver and muscle tissues 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 adequate written treatment records for veterinary drugs administered to your herd. Your records lack the dosage administered and the withdrawal times for milk and beef. Foods from animals held under such conditions are adulterated under Section 402(a)(4).

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You also caused the drug [REDACTED] containing sulfadimethoxine, to become adulterated within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with the approved labeling. The extralabel use in animals of an approved veterinary or human drug is permitted if it 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 [REDACTED] failed to comply with these requirements. For example, you used this drug at levels that exceeded the labeled dosage limits without the supervision of a licensed veterinarian, in violation of 21 CFR 530.11(a). Further, your extralabel use of [REDACTED] resulted in illegal drug residues, in violation of 21 CFR 530.11(d). Because your extralabel use of [REDACTED] was not in compliance with 21 CFR Part 530, the drug is unsafe under Section 512(a) of the Act. As a result, your use of this drug caused it to be adulterated within the meaning of Section 501(a)(5) of the Act.

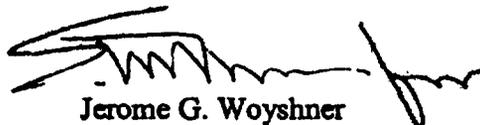
You should not consider this an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

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, such as 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 that was sold and 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 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 Richard T. Trainor, Compliance Officer, at the following address: FDA, 300 Hamilton Ave., White Plains, New York 10601.

Sincerely,



Jerome G. Woyshner
District Director