



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Charles H. Stewart, Owner
Stewart's Dairy
397 Mack Road
Addison, NY 14801

June 14, 2004

Ref: NYK-2004-18

Dear Mr. Stewart:

An inspection at your dairy farm located in Addison, New York, conducted by a Food and Drug Administration investigator on February 26 and March 18, 2004, confirmed that you offered an animal for sale for slaughter as 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 Act does not permit the extralabel use of medicated feeds, therefore your action causes the medicated feeds to be unsafe to use under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(6) of the Act.

On or about December 9, 2003, you consigned a bob veal calf (identified by U.S. Department of Agriculture ("USDA") Sample No. 435214, back tag no. [REDACTED], and retain tag no. [REDACTED]) for slaughter for human food through [REDACTED] located in [REDACTED]. USDA's FSIS analysis of tissue samples collected from that animal found 6.46 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, which 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 medicated animal feed is 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 and medicated feeds used on your animals. You also failed to maintain any treatment records for your calves. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

Moreover, your actions caused the medicated animal feed, "[REDACTED] Medicated Calf Milk Replacer" containing the drug neomycin to become adulterated within the meaning of Section 501(a)(6) of the Act. You used that product in calves to be processed for veal, contrary to the warning on their labels. Since the Act does not permit the extralabel use of medicated feeds, your actions cause these medicated feeds to be unsafe to use under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(6) of the Act

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.

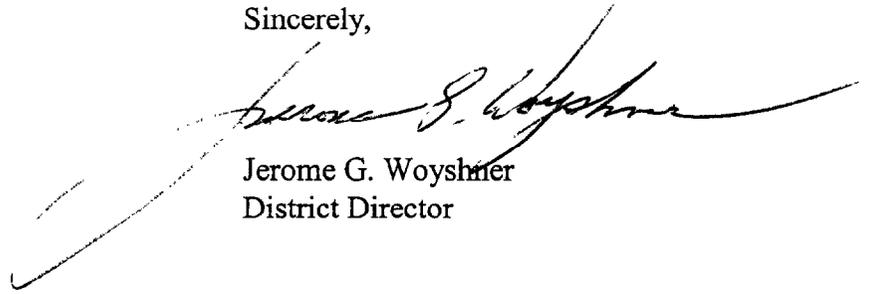
Please notify this office in writing, within 15 working days, of the steps you have taken to bring your dairy farm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. If corrective action cannot be completed 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.

Our records show that this is not the first unsafe drug residue associated with your dairy farm. Specifically, on or about August 12, 2003, you consigned a bob veal calf (identified by USDA Sample No. 431895, back tag no. '[REDACTED]', and retain sale 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 2.33 ppm of the drug neomycin in kidney tissue, 18.05 ppm of the drug sulfamethazine in liver tissue, and 27.42 ppm of the drug sulfamethazine in muscle tissue. There are no established tolerances for neomycin and sulfamethazine in calves (21 CFR 556.430 and 556.670).

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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. Woysner", written in a cursive style. The signature is positioned above the printed name and title.

Jerome G. Woysner
District Director