



DEPARTMENT OF HEALTH & HUMAN SERVICES

93442d

New York District

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

August 8, 2002

WARNING LETTER NYK 2002-40

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Brian A. Siple, Owner  
BCS Farms  
280 River Road  
Peru, New York 12972

Dear Mr. Siple:

An investigation conducted by U.S. Food and Drug investigators Michael G. Sinkevich and Scott M. Loughan at your dairy operation located in Peru, New York on June 13 and 14, 2002 confirmed that in March 2002 you offered a cow 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). The inspection also revealed you caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about March 12, 2002, you sold a cow identified with ear tag number 90 for slaughter as human food. The cow was later slaughtered at [REDACTED] USDA analysis of tissue samples collected from that animal on March 13, 2002 at [REDACTED] identified the presence of the drug sulfadimethoxine at a level of 2.29 ppm in the liver and 2.71 in the muscle. A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle (Title 21, *Code of Federal Regulations* (21 CFR), Section 556.640). The presence of this drug at the level reported 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 found that you hold animals under conditions whereby 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 and 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 in edible tissues. Food from animals held under such conditions is adulterated under the Act.

In addition, you caused the drug [REDACTED] containing sulfadimethoxine, which your farm uses on dairy cows, to become adulterated within the meaning of Section 510(a)(5) of the Act when you failed to use the drug in conformance with its approved labeling. Your use of this drug in dairy cows without following the labeled withdrawal period causes the drug to be unsafe and, therefore, adulterated.

Brian A. Siple  
Page 2

You should not consider this letter to be 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.

It is not necessary for you to have personally shipped 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 sold and subsequently offered for sale to a slaughterhouse which ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

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 being initiated by FDA without further informal notice. These actions may include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific 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 correct the violations and to prevent the recurrence of similar violations. Your response should be directed to Lisa M. Utz, Compliance Officer, at the above address.

Sincerely,



Jerome G. Woysner  
District Director

