



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

January 31, 2001

WARNING LETTER NYK 2001-40

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jay N. Martin, Owner
Jay N. Martin AKA Horizon Dairy
1675 Jenkins Road
Clyde, NY 14433

Dear Mr. Martin:

An investigation was conducted at your dairy farm operation located at 1675 Jenkins Road, Clyde, NY, by Investigator Russ E. Davis on November 20-22 & 27, 2000. The investigation confirmed that you offered two cows 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); and that you have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about June 6, 2000 you sold a cow bearing plastic farm tag No. [REDACTED] and sale tag No. [REDACTED] to [REDACTED], where permanent ear tag No. [REDACTED] was attached. This cow was subsequently delivered to and slaughtered at [REDACTED] on or about June 7, 2000. USDA analysis of tissue samples from that animal revealed the presence of the drug, penicillin, at a level of .18 ppm in the kidney. This exceeds the 0.05 ppm tolerance identified in 21 CFR 556.220 for uncooked edible tissues of cattle. The presence of penicillin at this level in kidney tissue causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about August 17, 2000 you sold a cow bearing plastic farm tag No. [REDACTED] and back tag No. [REDACTED] to [REDACTED] for sale for slaughter for food. This cow was later also identified with metal ear tag No. [REDACTED]. This cow was subsequently delivered to and slaughtered at [REDACTED] on or about August 18, 2000. USDA analysis of tissue samples from that animal revealed the presence of the drug, penicillin, at a level of .09 ppm in the kidney. This exceeds the 0.05 ppm tolerance identified in 21 CFR 556.220 for uncooked edible tissues of cattle. USDA analysis of tissue samples from that animal also revealed the presence of the drug, streptomycin, at a level of 4.58 ppm. There is no published

tolerance for streptomycin in the edible tissues of dairy cows. The presence of penicillin at this level and the presence of streptomycin in kidney tissue 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 which 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 a system for assuring that drugs are used in a manner not contrary to label instructions, and for assuring animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

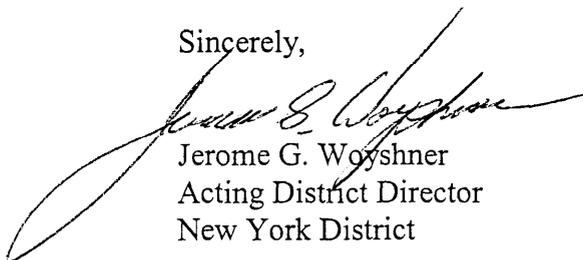
Our investigation also revealed you adulterated the drugs penicillin G procaine and penicillin-dihydrostreptomycin within the meaning of Section 501(a)(5) of the Act when you used the drugs in an extralabel manner without veterinary supervision. Your use of these drugs in dairy cows at higher than labeled dosages causes the drug to be unsafe to use.

You should take prompt action to prevent any subsequent 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. This may include seizure and/or injunction.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, it is your responsibility to assure your operations are in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. As a dairy farmer, you are the individual who introduces or offers for introduction into interstate commerce the adulterated animal. It is not necessary for you to personally ship an animal into 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 an auction barn and/or slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken, or intend to take, to prevent a recurrence of these or similar violations. Your response should be directed to Patricia A. Clark, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, NY 14202, telephone 716-551-4416, ext. 3165.

Sincerely,



Jerome G. Woyshner
Acting District Director
New York District