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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

April 6, 2004

WARNING LETTER NYK 2004-10

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Paul J. Wawrzyniak, Owner
Red Creek Farms
218 Schad Road
Alden, NY 14004

Dear Mr. Wawrzyniak:

An investigation was conducted at your dairy farm operation located at Red Creek Farms, 218 Schad Road, Alden, NY, by U.S. Food and Drug (FDA) Investigator Michael W. Burd from February 23 to March 9, 2004. The investigation confirmed that you offered three 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).

On or about February 26, 2003, you contacted [REDACTED], to transport a cow bearing farm tag 20 from Red Creek Farms, Alden, NY to [REDACTED]. [REDACTED] applied yellow back tag 458 and delivered the cow to [REDACTED]. This cow, which also bore ear tag 21WYU7968, was subsequently delivered to and slaughtered at [REDACTED], on or about February 28, 2003. USDA analysis of tissue samples from that animal revealed the presence of the drug flunixin at a level of 0.662 ppm in the liver. This level exceeds the 0.125 ppm tolerance identified in 21 Code of Federal Regulations (CFR) 556.286 by more than five times. The presence of flunixin at this level in cattle causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about October 20, 2003, you contacted [REDACTED], to transport two cows from Red Creek Farms, Alden, NY to [REDACTED]. These two cows were subsequently delivered to and slaughtered at [REDACTED], on or about October 21, 2003.

The first cow transported from your farm on or about October 20, 2003 bore your farm tag 284. It bore yellow back tag 830 applied by [REDACTED] at your farm, and back tag 21PL9378 when it arrived at [REDACTED]. USDA analysis of tissue samples from this animal revealed the presence of the drug sulfadimethoxine at a level of 1.02 ppm in the liver and 0.58 ppm in the muscle.

These levels exceed the 0.1 ppm tolerance identified in 21 Code of Federal Regulations (CFR) 556.640 by more than 10 times and five times, respectively. The presence of sulfadimethoxine at these levels in cattle causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

The second cow transported from your farm on October 20, 2003 bore your farm tag 275. It bore yellow back tag 831 applied by [REDACTED] at your farm, and back tag 21PL9385 when it arrived at [REDACTED]. USDA analysis of tissue samples from this animal revealed the presence of the drug sulfadimethoxine at a level of 0.24 ppm in the liver and 0.22 in the muscle. These levels also exceed the 0.1 ppm tolerance identified in 21 Code of Federal Regulations (CFR) 556.640. The presence of sulfadimethoxine at these levels in cattle 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. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

Our investigation also revealed you administered the drug Banamine (flunixin) to the cow bearing your farm tag 20 to treat a fever. Although you had no Banamine at your farm at the time of our investigation, we note label instructions for this drug state it is "not for use in lactating or dry cows". Use of Banamine in lactating or dry dairy cows constitutes extra-label use. Use of a drug contrary to label instructions (extra-label use) without veterinary supervision causes the drug to be unsafe within the meaning of Section 512 of the Act and adulterated under Section 501(a)(5) of the Act.

You should take prompt action to correct the above 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 injunction.

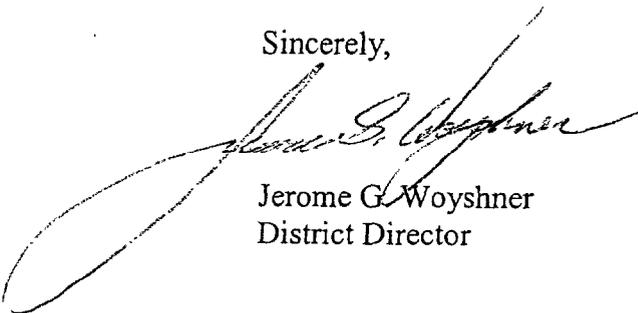
The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, it is your responsibility to assure your operations are in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. As a dairy farmer, you are the individual who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

Red Creek Farms

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Please notify this office in writing within 15 working days of the steps you have taken, or intend to take, to prevent 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, New York 14202, telephone 716-551-4461, ext. 3168.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jerome G. Woyshner". The signature is written in black ink and is positioned above the printed name and title.

Jerome G. Woyshner
District Director