



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

February 8, 2000

WARNING LETTER NYK 2000-30

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dennis H. Eldred, Owner
Willet Dairy, LP
329 Route 34
Locke, New York 13092

Dear Mr. Eldred:

As you know, we have performed an investigation of your dairy farms located at 423 State Route 34, Locke, New York; 176 Mahoney Road, King Ferry, New York; and West Corey Road, Venice Center, New York. Inspections were conducted by Investigator McNew on June 9 and 18, 1999; and Investigator Chilton on October 12-15, 21, and 22, 1999 and November 16, 1999. The investigations confirmed three cows you offered for slaughter were adulterated within the meaning of Sections 402 (a)(2)(C)(ii) and 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

- On or about March 24, 1999 you sold a dairy cow identified with barn tag number 5401 and metal DHI ear tag number 21ZBN5398/USDA sample number 270562, at Empire Livestock Marketing Inc., Dryden, New York. The cow was delivered to Taylor Packing Co., Inc., Wyalusing, Pennsylvania on March 25, 1999. USDA analysis of tissue samples from that animal revealed the presence of the drug, gentamicin, at a level of 3.40 ppm in the kidney. There is no published tolerance for gentamicin in the edible tissues of dairy cows. The presence of this residue caused this animal to be adulterated within the meaning of Section 402 (a)(2)(C)(ii) of the FD&C Act.
- On or about May 24, 1999 you sold a dairy cow identified with barn tag number 7202 and DHI ear tag number 21ZCY7202/USDA sample number 210573, at Empire Livestock Market Inc., Dryden, New York. The cow was delivered to Moyer Packing Co., Souderton, Pennsylvania on May 26, 1999. USDA analysis of tissue samples from that animal revealed the presence of the drug, gentamicin, at a level of 3.10 ppm in the kidney. Again, without a tolerance, dairy cows with gentamicin residues in their edible tissues are adulterated within the meaning of Section 402 (a)(2)(C)(ii) of the FD&C Act.
- On or about October 6, 1999 you sold a dairy cow identified with barn tag number 1082, DHI ear tag number 21ZCJ1677/USDA sample number 264857, at Empire Livestock Market Inc., Dryden, New York. The cow was delivered to Taylor Packing Co. Inc., Wyalusing, Pennsylvania on October 7, 1999. USDA analysis of tissue samples from that animal revealed the presence of the drug, sulfadimethoxine, at a level of 0.34 ppm in the liver. A tolerance of 0.1 ppm has been established for sulfadimethoxine in the edible tissues of dairy cows and is published in Title 21 Code of Federal Regulations 556.640. The presence of sulfadimethoxine in excess of the tolerance causes the food to be adulterated within the meaning of Section 402 (a)(2)(C)(ii) of the FD&C Act.

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Our investigation found that you hold animals under conditions which are so inadequate that diseased and/or medicated animals bearing potentially harmful drug residues in edible tissues are likely to enter the food supply. For example, you lack a system for assuring that animals have been treated only with drugs which have been approved for use in those species; 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 from edible tissues. Foods from animals held under such conditions are adulterated.

Our investigation revealed you adulterated the drugs, Gentocin brand of Gentamicin Sulfate solution and Flunixin Meglumine injection within the meaning of Section 501(a)(5) when you used the drugs in calves and dairy cows, a species for which they are not approved. Likewise, you used the drug Albon brand of Sulfadimethoxine bolus in a dairy cow without adhering to the labeled withdrawal period. Your uses of these drugs in the manner described caused them to be unsafe for use.

It is your responsibility to assure your operations are in compliance with the requirements of the 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.

Please notify this office in writing, within 15 days, of the steps you have taken, or intend to take, to prevent a recurrence of these or similar violations. It is noted that you made a number of verbal commitments to Investigator Chilton on October 22, 1999 and November 16, 1999 as well as providing him with copies of several blank documents on November 16, 1999. Your response should be directed to John Thompson, Compliance Officer, at the above address.

Sincerely,



Brenda J. Holman
District Director