



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

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

August 30, 2002

WARNING LETTER NYK 2002-46

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Richard R. Talcott, Co-Owner
Ashland Farms LLC
2620 State Route 34B
Aurora, NY 13026

Dear Mr. Talcott:

An investigation performed by U.S. Food and Drug Administration Investigator Steven J. Libal included an inspection of your dairy farm on April 4 & 11, 2002. The investigation confirmed 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). In addition, your extra label usage, caused the two drug products to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about August 8, 2001 you sold a cow identified with barn tag number 3133 for slaughter as human food at [REDACTED]. USDA analysis of tissue samples collected from that animal on August 9, 2001 at [REDACTED] identified the presence of 0.10 ppm penicillin in kidney tissue. A tolerance of 0.05 ppm has been established for residues of penicillin in edible tissues of cattle (Title 21 Code of Federal Regulations 556.510). 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.

On or about August 29, 2001 you offered a bob veal calf, assigned sale tag number L-617, for sale for slaughter as human food at [REDACTED]. USDA analysis of tissue samples collected from that animal on August 31, 2001 at Jerry Hayes Meats, Inc., Newark Valley, New York, identified the presence of 0.26 ppm sulfamethoxazole in the liver and 0.74 ppm sulfamethoxazole in the muscle. No tolerance has been established for residues of sulfamethoxazole in edible tissues of cattle.

Our investigation also found 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 on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

In addition, you are adulterating the veterinary drug penicillin G procaine, that your firm uses on cattle, within the meaning of Section 501(a)(5) when you fail to use it either in conformance with its approved labeling or, if used in an extralabel manner, in accordance with a lawful order of a licensed veterinarian and in compliance with extralabel use regulations at 21 CFR Part 530. You did not have a veterinarian's order for use of penicillin G procaine in the manner in which you used it, i.e. with an 11 day withdrawal period. Use of penicillin G procaine in a manner for which you did not have a veterinarian's order causes the drug to be unsafe within the meaning of section 512 of the Act. Additionally, because your use of penicillin G procaine resulted in the presence of a residue above the established tolerance in the edible tissue of cattle, your use of this drug was not in compliance with extralabel use regulations. 21 CFR 530.11(d). Your use of penicillin G procaine in a manner not in compliance with extralabel use regulations causes the drug to be unsafe within the meaning of section 512 of the Act.

You are also adulterating the human drug [REDACTED] of SULFAMETHOXAZOLE and TRIMETHOPRIM TABLETS, 800 mg/160 mg, within the meaning of Section 501(a)(5) when you fail to use it with a lawful order of a licensed veterinarian and in compliance with extralabel use regulations. You did not have a veterinarian's order to use this human drug in cattle in the manner in which you used it, i.e. with a one to three day withdrawal period. Use of the drug in a manner for which you did not have a veterinarian's order causes the drug to be unsafe within the meaning of section 512 of the Act. Additionally, because your use of this drug resulted in the presence of drug residue in edible tissue that might present a risk to public health, use of the drug was not in compliance with extralabel use regulations. 21 CFR 530.11(c). Your use of this drug in a manner not in compliance with extralabel use regulations causes the drug to be unsafe within the meaning of section 512 of the Act.

This letter is not intended to be an all-inclusive list of violations. 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 the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include seizure or injunction.

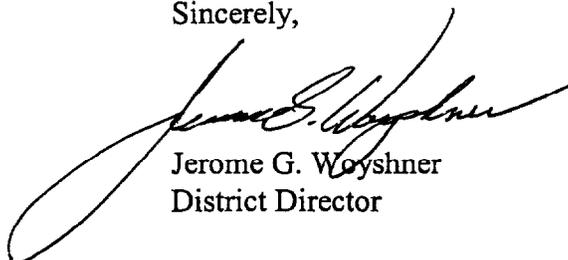
Ashland Farms LLC

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It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic 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 days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address.

Sincerely,



Jerome G. Woyshner
District Director

cc: Stephen R. Talcott, Co-Owner
Ashland Farms LLC
2620 State Route 34B
Aurora, New York 13026

cc w/cover ltr:

