



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 2002-47

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Charles L. Guard, DVM
Cornell University, College of Veterinary Medicine
Ithaca, New York 14853

Dear Dr. Guard:

An illegal tissue residue investigation performed by U.S. Food and Drug Administration Investigator Steven J. Libal included a visit to your veterinary practice on 5/1/02. The investigation revealed drug products you prescribed for extra-label use at Ashland Farms L.L.C., 2620 State Route 34B, Aurora, New York, were responsible for illegal tissue residues in two animals subsequently offered for slaughter for human food.

These include a sulfamethoxazole residue found in liver and muscle tissue from a veal calf slaughtered at [REDACTED], on 8/31/01, and an above tolerance penicillin residue found in kidney tissue of a culled dairy cow slaughtered at Taylor Packing Company, Inc., Wyalusing, Pennsylvania on 8/9/01. The presence of these drugs, at the reported levels, in edible tissues of these animals, causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Federal Food, Drug and Cosmetic Act (the Act). The fact that extra label usage resulted in residues which may present a risk to public health and which are above an established tolerance causes the drugs to be adulterated within the meaning of Section 501(a)(5) of the Act.

The sulfamethoxazole residue resulted from the extra label use at Ashland Farms of [REDACTED] of Sulfamethoxazole and Trimethoprim Tablets USP, 800 mg/160 mg double strength. The investigation revealed you prescribed this drug at Ashland Farms for treatment of arthritis in calves, and dispensed it at that location in a 500 tablet bottle. That product is not approved for use in cattle.

The penicillin residue resulted from the extra label use of penicillin G procaine, which you prescribed at that farm for extra label use at a dosage of [REDACTED]. The treatment regimen prescribed exceeds the four-day maximum treatment duration recommended on the drug labeling, and exceeds the recommended dosage limit per injection site.

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The extra label use of approved veterinary or human drugs by veterinarians is allowed under the Animal Medicinal Drug Use Clarification Act (AMDUCA), *provided that the regulations contained in Title 21 Code of Federal Regulations (21 CFR) Part 530 are followed.* A copy of those regulations was provided to you during Investigator Libal's visit on May 1, 2002. The regulations establish extralabel uses that are not permitted and which result in the drug being deemed unsafe within the meaning of Section 512 of the Act. Specifically, *extralabel use resulting in any residue which is above an established tolerance or which may present a risk to the public health* [21 CFR 530.11] is not permitted. The fact that a residue above the established tolerance and a residue which may present a risk to the public health occurred from the extralabel use you prescribed, makes this extralabel use not allowed under 21 CFR 530.11.

Our investigation revealed that at the time you prescribed Sulfamethoxazole and Trimethoprim Tablets, and penicillin G procaine, for extra label treatment at Ashland Farms, the animals for which the drugs were prescribed were held under conditions whereby animals bearing potentially harmful drug residues were likely to enter the food supply. For example, the farm lacked a system for assuring medicated animals were withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues, and treatment records were incomplete. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

21 CFR 530.20(a)(2) discusses what the veterinarian is required to do prior to prescribing or dispensing an approved new animal or human drug for an extralabel use. Specifically, the veterinarian must take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extralabel treatment. [21 CFR 530.20(a)(2)(iv)]. The fact that a residue occurred from extralabel use you prescribed indicates you did not comply with 21 CFR 530.20(a)(2)(iv).

21 CFR 530.12 requires that drugs for extra label use shall bear or be accompanied by labeling information adequate to assure the safe and proper use of the product. Your extra label use labeling for penicillin G procaine at Ashland Farms is inadequate because it lacks a recommendation for duration of therapy at the 20 cc per injection dosage level.

21 CFR 530.5 imposes recordkeeping requirements for veterinarians prescribing drugs for extra label usage. Our investigation revealed you are not complying with this regulation in that your extra label treatment records fail to identify the conditions treated, the species treated, the duration of treatment, or the number of animals treated.

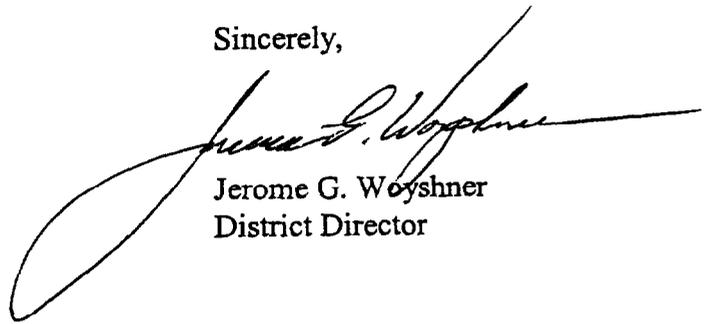
It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that the extra label drug usage prescribed by you resulted in the adulteration of animals that were subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for violations of the Act.

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You should take prompt action to correct these 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.

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,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner", with a long, sweeping horizontal line extending to the right.

Jerome G. Woyshner
District Director

cc: Bonni Voiland, Administrative Director
Cornell University, College of Veterinary Medicine
Ithaca, New York 14853