



DEPARTMENT OF HEALTH & HUMAN SERVICES

g 39531

New York District

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

April 9, 2003

WARNING LETTER NYK 2003-22

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Keith A. Scudder, DVM  
Rio Vista Veterinary Hospital  
9765 Smith Hill Road  
Painted Post, NY 14870

Dear Dr. Scudder:

An investigation performed by U.S. Food and Drug Administration Investigators Steven J. Libal and Andrew M. Abramowitz included visits to your veterinary practice on January 24 and 31, 2003. The investigation revealed you prescribed drug products for extra-label use at the [REDACTED] and that this resulted in illegal tissue residues in two animals offered for slaughter for human food. These include a flunixin residue of 2.47 PPM found in liver tissue from a cow slaughtered at [REDACTED] on July 19, 2002, and a penicillin residue of 0.65 PPM found in kidney tissue from a cow slaughtered at [REDACTED] on May 7, 2002.

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). Causing the use of an approved drug in a manner other than the approved, labeled conditions of use without meeting the requirements for exemption outlined in Title 21, Code of Federal Regulations, Part 530, causes the drugs to be adulterated within the meaning of Section 501(a)(5) of the Act.

The flunixin residue resulted from the extra-label use of [REDACTED] (Flunixin Meglumine) Injectable Solution in a lactating dairy cow at the [REDACTED]. The cow was administered a 15 cc intramuscular injection of [REDACTED] on July 12, 2002 for treatment of pneumonia, prior to being offered for sale for human food on July 18, 2002. Our investigation determined you routinely prescribed and dispensed [REDACTED] to this farm for use as [REDACTED] for treating lactating dairy cattle. [REDACTED] is not approved for use in lactating or dry dairy cattle.

The penicillin residue resulted from the extra-label use of penicillin G procaine in the treatment of a dairy cow at the [REDACTED]. The cow was administered two 20cc injections of [REDACTED] (Injectable Suspension) per day for three days, as a treatment for pneumonia prior to being sold for human food on May 6, 2002. The dosage administered is more than double the highest daily dosage (3000 units per pound of body weight) recommended on the product label, and exceeds the 10 ml recommended dosage limit per injection site. Our investigation determined that although the drug may have been purchased elsewhere, you prescribed the extra-label usage of penicillin G procaine for treatment of dairy cows at the [REDACTED].

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*. 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 residues above the established tolerance occurred from extralabel usage you prescribed, makes the extralabel uses not allowed under 21 CFR 530.11.

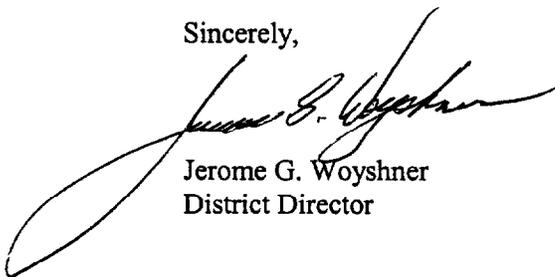
21 CFR 530.20(a)(2) requires a veterinarian to take certain steps prior to prescribing or dispensing an approved new animal or human drug for an extralabel use. One requirement mandates that the veterinarian take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extralabel treatment [21 CFR 530.20(a)(2)(iv)]. The fact that illegal residues occurred from extralabel use you prescribed indicates that you failed to comply with 21 CFR 530.20(a)(2)(iv).

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 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.

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,



Jerome G. Woyshner  
District Director

Enclosure: 21 CFR Part 530