



Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

October 27, 2003

WARNING LETTER NYK 2004-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Timothy J. Dennis, DVM, Partner
Eastview Veterinary Clinic P.C.
1260 State Route 14A
Penn Yan, New York 14527

Dear Dr. Dennis:

An investigation of your veterinary practice on June 2, 4, and 10, 2003 at Penn Yan, NY and an inspection of your client, [REDACTED] NY, by U.S. Food and Drug Administration (FDA) Investigator William P. Chilton have revealed serious deviations from Extralabel Drug Use In Animals, 21 Code of Federal Regulations (CFR) Part 530. Such deviations cause the approved animal drug [REDACTED] prescribed by you to be adulterated under Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act). The drug [REDACTED] is also misbranded within the meaning of Section 502(f)(1) because its labeling does not bear adequate directions for use.

The extralabel use of approved animal drugs by veterinarians is allowed under Section 512(a)(4) of the Act provided that the regulations contained in 21 CFR Part 530 are followed. Extralabel use of an approved animal drug that is not in compliance with the regulations contained in 21 CFR Part 530 renders the drug unsafe under Section 512 and thus adulterated under Section 501(a)(5) of the Act.

21 CFR 530.20(a)(2) requires a veterinarian to take certain steps prior to prescribing or dispensing an approved new animal drug for an extralabel use in food animals. You did not comply with several of these requirements when you prescribed and dispensed [REDACTED] for extralabel use at Mr. [REDACTED] dairy farm. Specifically:

- 1 The veterinarian must make a careful diagnosis and evaluation of the conditions for which the drug is to be used [21 CFR 530.20(a)(2)(i)]. Your Patient Medical Record for Mr. [REDACTED] for the period 8/17/02 through 5/26/03 shows veterinarians from this practice visited Mr. [REDACTED] dairy farm a number of times and prescribed and dispensed [REDACTED], 50 mg/mL, on four occasions. Mr. [REDACTED] was directed to use the drug for the treatment of all classes of adult dairy cattle at his discretion, without having a veterinarian diagnose and evaluate the conditions for which the drug was to be used.

2. The veterinarian must institute procedures to assure that the identity of the treated animal or animals is carefully maintained [21 CFR 530.20(a)(2)(iii)]. Specifically, as you stated in your June 10, 2003, affidavit, you have not instituted procedures to assure that the identity of treated animals are maintained and assigned withholding times have been satisfied.

In addition to the above, your prescription label for [REDACTED] fails to conform to 21 CFR 530.12 in that the labeling fails to include the class/species or identification of animals being treated, the dosage frequency and duration of treatment, and any appropriate cautionary statements. Such deviations cause the drug to be misbranded within the meaning of Section 502(f)(1) of the Act.

The above is not intended to be an all-inclusive list of violations. When you administer and/or dispense an animal drug for extralabel use in the treatment of food producing animals, you assume added responsibility. You must perform a careful medical diagnosis of the animal(s) to be treated, you must establish a substantially extended withholding period supported by appropriate scientific information, you must assure the identity of a treated animal and that treatment records are carefully maintained, and you must take appropriate measures to assure that assigned timeframes for withdrawal are met and that no illegal residues occur. You must also assure that any human or animal drug you prescribe or dispense for extralabel use has adequate labeling.

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 and/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 Richard T. Trainor, Compliance Officer, U.S. Food and Drug Administration, 300 Hamilton Ave., White Plains, New York 10601, telephone 914-682-6166 x34.

Sincerely,



Jerome G. Woyshner
District Director

cc: Glenn R. Fahnestock, DVM, Partner
Eastview Veterinary Clinic P.C.
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cc: Mark G. Huber, DVM, Partner
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