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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

July 25, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 36

James E. Van Over, DVM
Unity Veterinary Service
102 East Second Street, P.O. Box 128
Unity, Wisconsin 54488

Dear Dr. Van Over:

On March 29 and April 2, 2002, an investigator from the Food and Drug Administration (FDA) conducted an investigation involving the use of drugs in your veterinary practice. That investigation revealed serious deviations from the regulations for Extralabel Drug Use in Animals (Title 21, Code of Federal Regulations, Part 530 (21 CFR 530)). These deviations cause drugs compounded and prescribed by you to be unsafe under Section 512(a) of the Federal Food, Drug and Cosmetic Act (the Act) and, therefore, adulterated within the meaning of Section 501(a)(5) of the Act.

Your compounding and prescribing of Sulfamethoxazole in combination with other drugs for extralabel treatment failed to comply with the requirements in 21 CFR 530. Sulfonamide drugs are prohibited for use in lactating dairy cattle per 21 CFR 530.41(a)(9). The directions for use that you provided in the labeling did not preclude use in lactating dairy cattle. On the contrary, the labeling included a milk withhold time, which would indicate that treated animals could be used in milk production. Thus, you failed to meet the requirement of 21 CFR 530.12 that the drug bear or be accompanied by labeling information adequate to assure the safe and proper use of the product. The labeling also lacked other information required under 21 CFR 530.12, such as identification of the cattle being treated with the drug and a complete and accurate list of the established names of the active ingredients.

We enclose a copy of 21 CFR 530 for your ready reference. We strongly suggest that you review Part 530 and become familiar with all its requirements so that you can prevent future violations of the Act.

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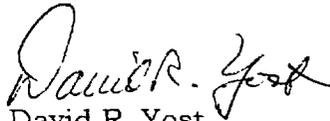
James E. Van Over, DVM
July 25, 2002

The above is not intended to be an all-inclusive list of violations. As a licensed veterinarian, you are responsible for complying with the extralabel use provisions of the Act and FDA's regulations when you compound, prescribe and administer animal drugs. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that your corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,



David R. Yost
Acting Director,
Minneapolis District

TGP/ccl

Enclosure: 21 CFR 530

