DEPARTMENT OF HEALTH AND HUMAN SERVICES 94999d

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7133
FAX: (612) 334-4142

September 2, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED **Refer to MIN 04 – 35**

Neal L. Womack, DVM
Curtis A. Leyk, DVM
Co-Owners
Lake Country Veterinary Service, P.A.
551 Railroad Avenue
Albany, Minnesota 56307

Dear Drs. Womack and Leyk:

On March 11 and 22, 2004, an investigator from the Minnesota Department of Agriculture, acting on behalf of the U.S. Food and Drug Administration (FDA), conducted an investigation involving the use of drugs in your veterinary practice. That investigation revealed that you caused animal drugs to be unsafe under Section 512(a) of the Federal Food, Drug, and Cosmetic Act (the Act) and adulterated within the meaning of Section 501(a)(5) of the Act because the drugs were used in a manner that did not conform with their approved uses or the regulations for Extralabel Drug Use in Animals, Title 21, Code of Federal Regulations (21 CFR), Part 530.

The extralabel use of approved veterinary or human drugs in animals is permitted only if it complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 CFR Part 530. Our investigation found that Lake Country Veterinary Service failed to comply with 21 CFR Part 530 in that you used sulfadimethoxine 12.5% oral solution in an extralabel manner by administering the drug intravenously to lactating dairy cattle. The extralabel use of sulfonamide drugs (such as sulfadimethoxine) in lactating dairy cattle is prohibited by 21 CFR 530.41(a)(9). Approved uses of sulfadimethoxine oral solution are listed in 21 CFR 520.2220a, copy enclosed.

You caused the aforementioned sulfadimethoxine animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of

the Act because the drug was prescribed and used in a manner that did not conform with its approved uses or the regulations for Extralabel Drug Use in Animals, 21 CFR Part 530.

The above is not intended to be an all-inclusive list of violations. As licensed veterinarians, you are responsible for complying with the requirements of the Act, including the extralabel use regulations promulgated under the Act. 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, such as seizure and/or injunction.

Our investigation revealed that your veterinary practice has verbally prescribed and/or administered 100 mg/mL oxytetracycline HCL injection in an extralabel manner to treat lactating dairy cattle. Prior to prescribing or dispensing an approved new animal drug for extralabel use in food animals, you must comply with 21 CFR 530(a)(2)(i)–(iv), which requires that the veterinarian:

> (i) make a careful diagnosis and evaluation of the conditions for which the drug is to be used;
>
> (ii) establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information, if applicable;
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> (iii) institute procedures to assure that the identity of the treated animal or animals is carefully maintained; and
>
> (iv) 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.

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

We acknowledge receipt of your July 29, 2004, letter, which addresses the findings from the March 11 and 22, 2004, inspection at your facility. We are not requesting any further response from you at this time, but be aware that failure to take prompt action to correct violations may result in regulatory action without further notice, such as seizure and/or injunction.

If you have questions about any of these issues, please contact Compliance Officer Timothy G. Philips at (612) 758-7133.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

TGP/cclx

Enclosures: 21 CFR 520.2220a
21 CFR 530