



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94336d
Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

September 30, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 38

Michael K. Strobush, DVM
President/Senior Veterinarian/Co-owner
Grassland Veterinary Service
115 Maple Street, Box 100
Granton, Wisconsin 54436

Dear Dr. Strobush:

On June 17 and 18, 2003, investigators 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.

Under Sections 512(a)(4)(A)(ii) and 512(a)(5)(B) of the Act, extralabel use of an approved animal or human drug in animals must comply with the regulations for extralabel drug use. Your compounding and prescribing of sulfamethoxazole and trimethoprim for extralabel treatment failed to comply with the requirements in 21 CFR 530. Sulfamethoxazole is prohibited for use in lactating dairy cattle per 21 CFR 530.41(a)(9). By compounding and prescribing these drugs for intramammary infusion to treat mastitis in lactating dairy cattle, you caused the drugs to be unsafe under Section 512(a) and thus adulterated under Section 501(a)(5).

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.

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.

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Michael K. Strobush, DVM
September 30, 2003

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,



W. Charles Becoat
Director
Minneapolis District

TGP/ccl
Enclosure: 21 CFR 530

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