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

September 13, 2001

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 01 - 76

John F. Thell, DVM  
Glencoe Veterinary Clinic, P.A.  
605 W. 13<sup>th</sup> Street  
Glencoe, Minnesota 55336

Dear Dr. Thell:

On July 10 and 20, 2001, investigators from the Food and Drug Administration (FDA) conducted an investigation involving tissue residues in cattle offered for slaughter as human food by . 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 prescribed and administered by you to be adulterated within the meaning of Section 501(a)(5) of the Federal Food, Drug and Cosmetic Act (the Act).

Your administration of phenylbutazone for extra-label treatment failed to comply with the requirements in 21 CFR 530. For example, you failed to provide labeling information (e.g. withholding time) adequate to assure safe and proper drug use. Animals treated by you were subsequently offered for slaughter as human food, and the United States Department of Agriculture found phenylbutazone residues. Thus, your deviations from 21 CFR 530 caused food to be adulterated within the meaning of 402(a)(2)(C)(ii).

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.

Our investigation also found that you administered dipyrone which is adulterated within the meaning of Section 501(a)(5) of the Act because it is an unapproved new animal drug. For your reference, we enclose a reproduction of an article published by FDA's Center for Veterinary Medicine (CVM) in 1996 regarding dipyrone

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products. Due to safety and efficacy concerns, dipyrone products should not be used, and these products are in violation of the Act.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal with a drug that was shipped in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended to be an all-inclusive list of violations. As a licensed veterinarian, you are responsible for ensuring that all drugs you prescribe and administer are not adulterated and that all requirements of the Act are met. 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,

  
Cheryl A. Bigham  
Acting Director  
Minneapolis District

TGP/ccl

  
Enclosure: *FDA Veterinarian Newsletter*, Jan/Feb 1996  
21 CFR 530

xc: Roland C. Olson, DVM  
Executive Director  
Minnesota Board of Veterinary Medicine  
2829 University Avenue SE, #540  
Minneapolis, MN 55414