



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

May 22, 2003

**WARNING LETTER**

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

Refer to MIN 03 - 21

Sam J. Holman, DVM  
Holman Veterinary Clinic  
1210 Second Avenue NW, P.O. Box 1434  
Aberdeen, South Dakota 57402-1434

Dear Dr. Holman:

On January 14 and 15, 2003, an investigator from the Food and Drug Administration (FDA) conducted an inspection involving the use of drugs in your veterinary practice. That inspection found significant violations of the Federal Food, Drug, and Cosmetic Act (the Act) and deviations from the regulations for Extralabel Drug Use in Animals [Title 21, Code of Federal Regulations, Part 530 (21 CFR 530)].

Extralabel use of approved animal and human drugs is permitted under Sections 512(a)(4)(A) and 512(a)(5) of the Act if the drug is used (i) by or on the order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship; and (ii) in compliance with regulations at 21 CFR Part 530. Because you dispensed drugs without a valid veterinarian-client-patient relationship and because you did not dispense such drugs in conformance with 21 CFR Part 530, the drugs you dispensed were unsafe under Section 512(a) of the Act and adulterated under Section 501(a)(5). Specifically, you have compounded and distributed the following animal drug products for extralabel use without complying with 21 CFR 530:

AM-500 Calf Scour Capsules  
AX-500 Calf Scour Capsules  
Type K Calf Scour Capsules  
Rx H-50-H  
P101

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Deviations from 21 CFR 530 include:

- a. Failure to maintain a valid veterinarian-client-patient relationship (VCPR) as defined in 21 CFR 530.3(i) and as required by 21 CFR 530.20(a)(1).
- b. Compounding and distribution of new animal drugs without determining that there are no approved animal or human drugs that would be effective in treating the condition(s) diagnosed. 21 CFR 530.13(b)(2).
- c. Compounding from human drugs where an approved animal drug could have been used. 21 CFR 530.13(b)(2).
- d. Compounding and distribution of drug products that lack required labeling. For example, the labeling for the Calf Scour Capsules and the P101 lack withhold time, and the Rx H-50-H lacks identification of the animal to be treated. 21 CFR 530.12(c).

These deviations cause drugs you compounded and distributed to be unsafe under Section 512(a) of the Act and, therefore, adulterated within the meaning of Section 501(a)(5) of the Act. The compounded drugs are also misbranded under Section 502(f)(1) because they do not bear adequate directions for use.

You have also sold medicated feed premixes that are unsafe under Section 512(a)(2)(C) of the Act and, therefore, adulterated under Section 501(a)(6) because the medicated feed labeling does not conform to the published conditions and indications of use. Such medicated feeds are also misbranded under Sections 502(c) and 502(f)(1) of the Act because information required under the authority of the Act to appear on the label is missing and because the labels do not bear adequate directions for use. Specifically:

- a. Super Vita Zest contains chlortetracycline, which is covered under regulations in 21 CFR 558.128 (copy enclosed). The Super Vita Zest labeling lacks the species of animal to be fed and directions for use as required by this regulation.
- b. Holman Vitamin Premix W/S contains oxytetracycline, which is covered under 21 CFR 558.450 (copy enclosed). The Holman Vitamin Premix W/S labeling lacks directions for use as required by this regulation.

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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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.

We have received FDA-483 responses dated January 4 and February 16, 19, 20 and 21, 2003. Those communications attempt to explain why you have been unable to comply with the law and regulations. In your letter dated February 16, 2003, you stated that you would be retiring on March 3, 2003. In addition, in a February 20, 2003, fax, Tandy Holman reported that you understood that the products in question cannot be compounded.

You should update 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  


Enclosures: 21 CFR 558.128  
21 CFR 558.450  
21 CFR 530