



Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7124
FAX: (612) 334-4134

March 4, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 16

Richard Wedig, DVM
Co-owner
Prairie Veterinary Associates
918 Windsor Street
Sun Prairie, Wisconsin 53590

Dear Dr. Wedig:

On November 21, 25 and 26, 2003, an investigator from the Food and Drug Administration (FDA) conducted an investigation into two illegal tissue residues in dairy cows sold for slaughter as human food by [REDACTED]. That investigation included a review of your involvement with the aforementioned residues. The investigation revealed serious deviations from the regulations for Extralabel Drug Use in Animals, Title 21, Code of Federal Regulations (21 C.F.R.), Part 530. These deviations caused animal drugs to be used in a manner that was unsafe under Section 512(a) of the Federal Food, Drug and Cosmetic Act (the Act) [21 U.S.C. § 360b(a)] and adulterated within the meaning of Section 501(a)(5) of the Act [21 U.S.C. § 351(a)(5)].

On August 19, 2003, [REDACTED] offered a dairy cow (backtag number 35HW6741) for slaughter as human food. The cow was slaughtered at [REDACTED]. The USDA analysis of tissue samples collected from this cow identified the presence of flunixin at 2.848 ppm in the liver. Flunixin is not approved for use in lactating or dry dairy cows [per 21 C.F.R. § 522.970(e)(2)(iii)]. The presence of flunixin in the edible tissues of this food animal caused it to be adulterated under Section 402(a)(2)(C)(ii) of the Act.

On August 21, 2003, [REDACTED] offered a dairy cow (backtag number 35HW6479) for slaughter as human food. The cow was also slaughtered at [REDACTED]. USDA analysis of tissue samples collected from this cow

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identified the presence of sulfadimethoxine at 0.19 ppm in the liver and 0.25 in the muscle. A subsequent investigation found that you had prescribed and dispensed sulfadimethoxine 12.5% oral solution for extralabel use by administering it intravenously in lactating dairy cattle. The extralabel use of sulfonamide drugs in lactating dairy cattle is prohibited by 21 C.F.R. 530.41(a)(9), therefore, the presence of sulfadimethoxine in the edible tissues of this food animal also caused it to be adulterated under Section 402(a)(2)(C)(ii) of the Act.

The extralabel use of approved veterinary or human drugs is permitted only if it complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 C.F.R. Part 530. Our investigation found that you failed to comply with 21 C.F.R. Part 530 in that:

- Flunixin is not approved for use in lactating or dry dairy cows (21 C.F.R. 522.970, copy enclosed). You prescribed and dispensed flunixin for extralabel use, and that extralabel use of flunixin caused an illegal drug residue in a cow sold for human food. 21 C.F.R. 530.11(d) prohibits any extralabel use that results in a residue above an established tolerance.
- You prescribed and dispensed sulfadimethoxine 12.5% oral solution for extralabel use (administration of the product intravenously) in lactating dairy cattle. The extralabel use of sulfonamide drugs in lactating dairy cattle is prohibited by 21 C.F.R. 530.41(a)(9). Approved uses of sulfadimethoxine 12.5% oral solution are cited in 21 C.F.R. 520.2220a (copy enclosed).

These regulations require, among other conditions, that:

1. Prior to prescribing or dispensing an approved new animal drug for an extralabel use in food animals, the veterinarian must:
 - Establish a substantially extended withdrawal period prior to marketing of milk, meat, or other edible products supported by appropriate scientific information.
 - Institute procedures to assure that the identity of the treated animal or animals is carefully maintained.
 - Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subject to extralabel treatment.
2. The new animal drug prescribed or dispensed for extralabel use must bear or be accompanied by labeling information which is adequate to assure the safe and

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proper use of the product. At a minimum, the following label information is required:

- The name and address of the prescribing veterinarian.
- The established name of the drug (active ingredient), or if formulated from more than one ingredient, the established name of each ingredient.
- Any directions for use specified by the veterinarian (including the class/species or identification of the animal or group of animals; and the dosage, frequency, route of administration, and duration of therapy).
- Any caution statements.
- The veterinarian's specified withdrawal/discard time(s) for meat, milk, or any other food which might be derived from the treated animal(s).

Because you failed to comply with the requirements of 21 C.F.R. Part 530 in prescribing and dispensing animal drugs, your customer used new animal drugs in an unapproved manner without meeting the requirements for extralabel use set forth in Section 512(a)(4)(A) and 21 C.F.R. Part 530, thereby rendering the drugs unsafe under Section 512 of the Act and adulterated under Section 501(a)(5) 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 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.

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

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.

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Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated on the letterhead.

Sincerely,


W. Charles Becoat
Director
Minneapolis District

TSW/ccl


Enclosures: 21 C.F.R. 520.2220a
21 C.F.R. 522.970
21 C.F.R. Part 530

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