DEPARTMENT OF HEALTH AND HUMAN SERVICES

95000d

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 – 34

David L. McMahan
Owner
Redfield Feed Service
1120 E. Seventh Avenue
Redfield, South Dakota 57469

Dear Mr. McMahan:

On May 18-19, 2004, an investigator from our office conducted an inspection of your feed and veterinary service. That inspection revealed that your firm is selling and dispensing veterinary prescription drug products without a lawful order from a licensed veterinarian. Because you dispensed these prescription new animal drugs without the lawful written or oral order of a licensed veterinarian while held for sale, they are misbranded within the meaning of Section 503(f)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act). Examples of prescription drugs that your firm is dispensing without an order from a licensed veterinarian include: sulfamethoxazole/trimethoprim, florfenicol (~~~), tilmicosin (~~~), enrofloxacin (~~~), dinoprost tromethamine (~~~), and dexamethasone.

In addition, these prescription drugs are misbranded within the meaning of Section 502(f)(1) of the Act because they do not bear adequate directions for use, and they do not fall into an exception to that requirement. FDA has defined "adequate directions for use" as "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 CFR 201.5. Directions under which a layperson can safely use prescription animal drugs cannot be written because such drugs can only be used safely under the professional supervision of a licensed veterinarian. Thus, adequate directions for lay use cannot be written for these prescription new animal drugs. These drugs are not exempt from Section 502(f)(1) because they fail to comply with the conditions set forth in Section 503(f)(2)(A) and 21 CFR 201.105 in that they were not sold by or upon the lawful

written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

You, as the owner of this firm, and [redacted], DVM, have the responsibility to insure that all prescription drugs intended for veterinary use that are dispensed or sold by your firm are done so only upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

Further, we advise you that 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. 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.

The above is not intended to be an all-inclusive list of violations. 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 promptly correct these violations may result in regulatory action without further notice. These sanctions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within 15 working days of receiving this letter of the specific steps you have taken to correct the noted violations, including an explanation of steps being taken to prevent the recurrence of similar violations. Also, include copies of any available documentation demonstrating that corrections have been made. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time period within which the corrections will be completed.

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