



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94936d

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 1, 2004

**WARNING LETTER**

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

Refer to MIN 04 - 33

Dayton H. Kloss  
Owner  
Hitchcock Feed Service  
317 Clark Street  
Hitchcock, South Dakota 57348

Dear Mr. Kloss:

On May 20, 2004, an investigator from our office conducted an inspection of your retail feed store. That inspection revealed that your firm is selling and further dispensing prescription veterinary drug products, such as *MV* (florfenicol) and *W* (flunixin), without an order from a licensed veterinarian.

These prescription drugs are misbranded within the meaning of Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (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.

In addition, 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 Act.

Page Two

Dayton H. Kloss  
September 1, 2004

The above is not intended to be an all-inclusive list of violations. You are responsible for complying with the requirements of 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. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within 15 working days of your receipt of 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 fifteen (15) working days, state the reason for the delay and the time period within which the corrections will be completed.

Our inspection also found that you may be using prescription veterinary drugs in an extralabel manner to treat your own cattle. You stated that *mm* brand gentamicin sulfate, which was being stored in the cooler at your feed store, was purchased for use on your own cattle. Gentamicin is not approved for use in cattle. The 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 correct and prevent violations of the Act.

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 *aj*

Enclosure: 21 CFR 530