



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
M35747

WARNING LETTER

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

March 23, 2000

00-PHI-13

Merle R. Ressler, Partner
Richard L. Thompson, Partner
Amos S. Fisher, Partner
Fisher and Thompson
15 Newport Road
Leola, PA 17540

Gentlemen:

An inspection of your veterinary drugs sales facility by Food and Drug Administration Investigator Calvin W. Edwards in October and November 1999 and January 2000, revealed the illegal purchase, holding, and sale of veterinary prescription drugs. You caused these violations in that you failed to establish controls to assure that prescription veterinary drugs are sold only upon a written or other order of a licensed veterinarian based on a valid veterinarian/client/patient relationship. Such purchase, holding, and sale are serious violations of Sections 502(f)(1) and 503(f)(1) of the Federal Food, Drug, and Cosmetic Act (the Act).

These prescription veterinary drugs (Rx gentamicin sulfate) are misbranded while held for sale after shipment in interstate commerce because they have lost their exemption from the requirement to bear adequate directions for use set forth under Title 21, Code of Federal Regulations (21 CFR), Part 201.105. These prescription veterinary drugs fail to bear adequate directions for use in accordance with Section 502(f)(1) of the Act. Adequate directions for use means adequate directions for lay use. A prescription veterinary (animal) drug labeled, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian," is a drug which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian and is a drug for which adequate directions for lay use cannot be written.

Prescription veterinary drugs are exempt from statutory requirements for adequate directions for lay use only when they are in the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of drugs that are to be used by or on the prescription or other order of a licensed veterinarian.

Warning Letter: Fisher and Thompson Inc.

Prescription veterinary drugs are also exempt from the statutory requirements for adequate directions for lay use when they are in the possession of a retailer, hospital, clinic, or other person authorized under State law to dispense veterinary prescription drugs who is regularly and lawfully engaged in dispensing drugs that are to be used only by or on a prescription or other order of a licensed veterinarian in accordance with the regulations in 21 CFR Part 201.105 prescribed under the authority of Section 503(f)(1) of the Act.

The violations addressed above are not intended to be all inclusive of all products your firm distributes. You, as a part owner of this firm, have a responsibility to insure that all drugs intended for veterinary use, which bear the veterinary legend "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" are dispensed or sold by you or your firm on the order of a prescription or other order of a licensed veterinarian based upon a valid veterinarian/client/patient relationship.

A valid veterinarian/client/patient relationship, as defined by the American Veterinary Medical Association, is the following:

An appropriate veterinarian/client/patient relationship, will exist when: (1) the veterinarian has assumed the responsibility for making medical judgements regarding the health of the animal(s) and the need for medical treatment, and the client (owner or other caretaker) has agreed to follow the instructions of the veterinarian; and when (2) there is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that a veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) is kept; and when (3) the practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy.

Our inspection also revealed that your route salesman, [REDACTED] recommended the use of gentamicin for the treatment of mastitis in dairy cows. Use of gentamicin to treat mastitis in dairy cows constitutes "extra-label use" of the product. "Extra-label use" refers to the actual or intended use of a new animal drug in a food-producing animal in a manner that is not in accordance with the drug product labeling.

Warning Letter: Fisher and Thompson Inc.

Under the Act, use of a drug in a manner different from that set forth in the approved labeling would cause the drug to be adulterated. In the past, FDA would permit the extra-label use of approved drugs in food-producing animals under very specific criteria as a discretionary policy. That policy required an extra-label use decision to be made by a veterinarian based on a valid veterinarian/client/patient relationship and other factors, and could not result in a residue in edible animal tissue. The Animal Medicinal Drug Use Clarification Act (AMDUCA) passed by Congress in October, 1994 and the implementing regulations (21 CFR Part 530) which were effective December 9, 1996, permit the extra-label use of approved human and veterinary drugs in food-producing animals only under very specific criteria as a matter of law rather than as a discretionary policy. Under AMDUCA, extra-label use must be by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and that use may not result in any residue which may present a risk to the public health. The decision to use a product in an extra-label manner may not be made by a layperson.

You should take prompt action to correct this violation and establish procedures to prevent its recurrence. Failure to promptly correct this violation may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within fifteen (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 reoccurrence of similar violations. If the corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of available documentation demonstrating that correction has been accomplished.

Your reply should be sent to the attention of James C. Illuminati, Compliance Officer, at the address referenced above.

Sincerely,



Thomas D. Gardine
District Director
Philadelphia District

Page 4

Warning Letter: Fisher and Thompson Inc.

Enclosures:

- 1) 21 CFR Part 201.105 Exemptions From Adequate Directions for Use, Veterinary Drugs
- 2) 21 CFR Part 530 Extra Label Drug use in Animals
- 3) Sections 502(f)(1) and 503(f)(1) of the Act

cc: PENNSYLVANIA STATE DEPARTMENT OF AGRICULTURE
Bureau of Animal Health and Diagnostic Services (BAHDS)
2301 North Cameron Street
Harrisburg, PA 17120
Attn: Dr. John I. Enck, Director

 Route Salesmen