



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
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April 12, 2004

Warning Letter No. 2004-NOL-22

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Howard S. Warner, DVM
Meredith-Warner Animal Clinic
1370 Nashville Highway
Lewisburg, Tennessee 37091-2220

Dear Dr. Warner:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a cow that originated from [REDACTED]. An investigation of your veterinary medical practice located in Lewisburg, Tennessee on January 15, 2004 by the FDA revealed serious deviations from the Extralabel Drug Use in Animals regulations (Title 21, *Code of Federal Regulations*, Part 530 (21 CFR Part 530)).

On October 23, 2003, [REDACTED] offered a cow, identified by back tag number 1969, for slaughter as human food. The cow was later slaughtered at [REDACTED]. USDA analysis of tissue samples collected from that cow identified the presence of 0.46 parts per million (ppm) of gentamicin in the kidney tissue. There is no established tolerance for gentamicin in cattle (Title 21 *Code of Federal Regulations*, Part 556.300). The presence of this drug in the edible tissue from this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

The FDA inspection revealed that you prescribed and dispensed gentamicin sulfate for the treatment of this cow. Your dispensing of gentamicin sulfate for extralabel treatment caused the food to become adulterated and failed to comply with 21 CFR Part 530, Extralabel Drug Use in Animals. For example, you failed to provide labeling information (e.g., directions for use and withholding time) adequate to assure safe and proper drug use. Therefore, the gentamicin is adulterated under section 501(a)(5) of the Act in that it is unsafe within the meaning of Section 512 of the Act.

The following conditions must be met for an extralabel use in food-producing animals of approved new animal drugs:

Prior to prescribing or dispensing an approved new animal drug for an extralabel use in food animals, the veterinarian must:

- Make a careful diagnosis and evaluation of the condition for which the drug is to be used.
- Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, 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.

The prescribed or dispensed drug bears labeling information which is adequate to assure the safe and proper extralabel use of the product. At a minimum, the following label information is recommended:

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

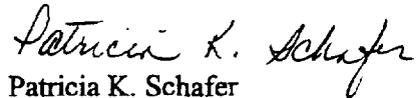
This letter may not list all the deviations at your practice. It is your responsibility to ensure that all requirements of the Act and its implementing regulations are met.

You should take prompt action to correct these violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of the steps you have taken to bring your practice into compliance with the law. Your response should include each step taken to correct the violations and prevent their recurrence. If you cannot complete all corrections within 15 working days, explain the reason for your delay and state when any remaining deviations will be corrected. Please include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Kari L. Batey, Compliance Officer, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Patricia K. Schafer
Acting Director, New Orleans District

cc: Jimmie D. Hopper, Director
Division of Quality and Standards
Tennessee Dept. of Agriculture
Ellington agricultural Center
Melrose Station, PO Box 40627
Nashville, TN 37204