



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

January 18, 2002

VIA FEDERAL EXPRESS

Wyatt C. Galbraith, D.V.M.
Animal Clinic
617 W. Popular St.
Pulaski, TN 38478

WARNING LETTER – 02-NSV-09

Dear Dr. Galbraith:

An inspection at your veterinary clinic located in Pulaski, TN was conducted by our investigator on November 27 - 28, 2001. The inspection was initiated in response to a United States Department of Agriculture (USDA) report regarding an illegal gentamicin residue in a cow offered for sale and slaughter for human food by [REDACTED].

The inspection revealed that you prescribed and dispensed gentamicin sulfate for the treatment of this cow. Your actions caused food to become adulterated with illegal drug residues within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In addition, you caused an animal drug to become adulterated and misbranded within the meaning of Sections 501(a)(5) and 502(f)(1) of the Act, respectively. You can find this Act and associated regulations through links in FDA's homepage at www.fda.gov.

On or about October 24, 2001, [REDACTED], offered a cow, identified by back tag number 63IW 7890, 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 7.12 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 (21 CFR), 556.300). The presence of this drug in the edible tissue from this animal causes the food to be adulterated.

Our inspection found that your administration of Vedco GentaVed Injection containing gentamicin sulfate for extralabel treatment 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(a)(1)(A) of the Act.

This letter may not list all the deviations at your facility. As a licensed veterinarian, you are responsible for ensuring that all drugs you prescribe and administer are not adulterated and that all requirements of the Act are met.

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It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should take prompt action to correct these 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 fifteen (15) working days of the steps that 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, we expect you to explain the reason for your delay and state when any remaining deviations will be corrected. Please include copies of any documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Karen Gale Sego, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,



Carl E. Draper
Director, New Orleans District

KGS:man

cc: w/copy 483:

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