



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

M2080 N
PHILADELPHIA DISTRICT

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

Telephone: 215-597-4390

WARNING LETTER

October 1, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Norman Smith, V.M.D.
RD #3
P.O. Box 214
Shippenville, PA 16254

Dear Mr. Smith:

On August 19, 1998 Food and Drug Administration (FDA) Investigator Robert T. Vaughn conducted an inspection at your office/clinic located on RD #3 in Shippenville, Pennsylvania, in response to a United States Department of Agriculture (USDA) report regarding an illegal drug residue in a cow which was offered for sale and slaughter for human food by [REDACTED]. Additional investigation by the FDA at the [REDACTED] has revealed serious violation of Sections 402(a)(2)(C)(ii) and 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about April 8, 1998, [REDACTED] offered a cow, back tag #3957, for slaughter as human food at [REDACTED]. The subject cow was purchased by [REDACTED] on April 8, 1998 and was slaughtered for food on April 9, 1998. USDA testing revealed the presence of 6.90 parts per million gentamicin in the kidney tissue of the animal. Gentamicin is not approved for oral or injectable use in cattle, and therefore, there is no tolerance for the presence of this drug in edible bovine tissue. The presence of gentamicin in the edible tissues from this animal renders the food from the animal to be adulterated under Section 402(a)(2)(C)(ii) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

Our inspection at the [REDACTED] revealed that the subject cow was treated for [REDACTED] with [REDACTED] without veterinary oversight. During the inspection [REDACTED] indicated that the [REDACTED] used to treat the subject cow was ordered for them by you. They also indicated that you

provided them with no directions for use or a withholding time for slaughter for the drug.

Inspection at your facility on August 19, 1998 revealed that you did order [REDACTED] for the [REDACTED]. During the inspection you indicated that the drug was for their use in treating their animals for [REDACTED]. You also indicated that the [REDACTED] were responsible for the diagnosis and treatment of their animals. You indicated that you did not provide the [REDACTED] with directions for use or a withhold time for slaughter for Gentocin.

The [REDACTED] used by the [REDACTED] is adulterated under Section 501(a)(5) of the Act within the meaning of Section 512. Section 512 in part deems a new animal drug unsafe unless an FDA approved application is in effect and the drug, its labeling and use conform to such approved application. [REDACTED] which was administered to the subject [REDACTED] cow [REDACTED] is not an approved treatment for [REDACTED], and is not labeled for such use, and use of this drug in an adult cow causes this drug to be adulterated.

While gentamicin is not approved for use in cattle, under certain circumstances a veterinarian may consider such "extra-label use", as described above, when the health of the animal is immediately threatened and suffering or death would result from failure to treat the affected animal. 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 labeling. 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.

The Animal Medicinal Drug Use Clarification Act (AMDUCA) passed by Congress in October of 1994 and the implementing regulations (Title 21 Code of Federal Regulatory (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 done by a layperson.

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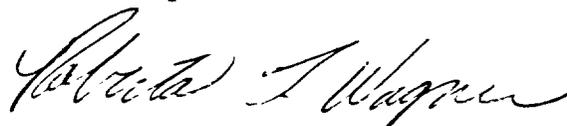
The above is not intended as an all-inclusive list of violations. It is, therefore, incumbent on you to take added precautions such as providing detailed written and verbal instructions and cautions to all producers/animal handlers, explaining the potential consequences of failure to follow your instructions, limiting the quantity of the drug provided, instituting a method of animal identification to assure that treated animals are readily recognized as such, and following-up to ensure that the instructions regarding use of the drug and the prescribed withdrawal times are followed.

You should take prompt action to correct the above violation and establish procedures whereby such violation does not recur. Failure to do so may result in regulatory action without further notice such as injunction and/or prosecution.

You should notify this office in writing within 15 days of the steps you have taken to bring your practice into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, state the reasons for the delay and the timeframe in which correction will be achieved. Please include copies of any available documentation demonstrating that correction has been accomplished.

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

Sincerely,



Roberta F. Wagner
Acting District Director
Philadelphia District

jci

Enclosure: Title 21 Code of Federal Regulations, Part 530
Extralabel Drug Use In Animals