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New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

July 7, 2000

WARNING LETTER NYK 2000-83

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James E. O'Shea, DVM
Tri-County Veterinary Medicine, LLC
5033 State Highway 8
New Berlin, New York 13411

Dear Dr. O'Shea:

On January 27 and February 1 and 2, 2000 a U.S. Food and Drug Administration investigator conducted an inspection of your veterinary clinic located in New Berlin, New York. The inspection was initiated in response to two United States Department of Agriculture (USDA) reports regarding illegal gentamicin residues in cows offered for sale and slaughter for human food by [REDACTED]. The inspection revealed you prescribed and dispensed Gentocin containing gentamicin sulfate for the treatment of these cows. Food containing illegal drug residues is adulterated within the meaning of Section 402 (a)(2)(C)(ii) of the Federal Food, Drug and Cosmetic Act (the Act). The inspection also revealed that you caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about [REDACTED] offered a cow identified with ear tag [REDACTED] for slaughter as human food. The cow was slaughtered on [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of 2.70 parts per million (ppm) gentamicin. There is no permitted level for residues of gentamicin in edible tissues of cattle. The presence of this drug in kidney tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about [REDACTED] offered a cow identified with ear tag [REDACTED] for slaughter as human food. The cow was slaughtered on [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of 2.90 parts per million (ppm) gentamicin. There is no permitted level for residues of gentamicin in edible tissues of cattle. The presence of this drug in kidney tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

The gentamicin used by [REDACTED] is adulterated under Section 501(a)(5) within the meaning of Section 512 of the Act. Section 512 deems, in part, a new animal drug is unsafe unless an FDA approved application is in effect and the drug, its labeling and use conform to such approved application or the implementing regulations for "Extralabel Drug Use In Animals," 21 Code of Federal Regulations Part 530.

The Animal Medicinal Drug Use and Clarification Act (AMDUCA) passed by Congress in October 1994 and the implementing regulations which became effective December 9, 1996, permit the extralabel use of approved human and veterinary drugs in food-producing animals only under very specific criteria.

Inspection at your facility revealed you prescribed and dispensed Gentocin containing gentamicin sulfate to ~~XXXXXXXXXXXXXXXXXXXX~~ for the treatment of scours in calves and coliform mastitis in cows; it is labeled by your clinic with directions for use in septicemia and mastitis. Gentamicin is not approved for these uses. Under certain conditions, a veterinarian may consider extralabel use when the health of the animal is immediately threatened and suffering or death would result from failure to treat the affected animal.

You did not meet these conditions. Extralabel 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 above its tolerance. There is no tolerance for gentamicin. The decision to use a drug in an extralabel manner may not be made by a layperson. AMDUCA also requires that drugs be labeled with the established name of each active ingredient. According to our investigation, White's is a mixture of gentamicin and dexamethasone. Your label for this product does not list the dexamethasone.

When you prescribe and dispense animal drugs for extralabel use in the treatment of disease conditions in food-producing animals, you assume added responsibility. You must establish a substantially extended withholding period supported by appropriate scientific information, you must assure the identity of a treated animal is carefully maintained, and you must take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal residues occur. This includes assuring that your clients will follow your instructions.

The above is not intended to be an all-inclusive list of violations at your facility. It is, therefore, incumbent upon you to take added precautions such as providing detailed written and verbal instructions and cautions to all producers and animal handlers explaining the potential consequences of failing to follow your instructions. You should also limit the quantity of the drug provided, institute a method of animal identification to ensure treated animals are readily identified as such, and follow up with your clients to ensure the instructions regarding the use of the drug and prescribed withdrawal times are followed.

We acknowledge that you do not intend to dispense gentamicin containing products any longer. Although this may prevent further gentamicin residues, you should assure that all animal drugs dispensed or prescribed by your firm are in compliance with the Act and the regulations. Failure to achieve prompt corrective action may result in regulatory action, without further notice. This may include seizure and/or injunction.

Please notify this office in writing, within 15 working days, of the steps you have taken to bring your practice into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. Your response should be directed to Lisa M. Utz, Compliance Officer, at the above address.

Sincerely,



Brenda J. Holman
District Director

