



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HF1-35

01-BLT-08

MSD 7, 1

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

December 5, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Charles R. Bray, Co-owner
Taylorsville Veterinary Clinic
4339B Ridge Road
Mount Airy, Maryland 21771

Dear Dr. Bray:

An FDA inspection of your veterinary clinic located in Mount Airy, Maryland, was conducted in follow-up to the findings of illegal drug residues of Gentamicin in cows located on three farms in Maryland that were treated for mastitis using D.G.S. (Lincomix, Dexamethazone, Gentocin and Spectam) manufactured and prescribed by your veterinary clinic. The D.G.S. is manufactured, in part, using Gentamicin Sulfate, labeled for use in the treatment of horses only. After treatment, the cows were sold for slaughter for use as human food. The residues, as detected by the United States Department of Agriculture (USDA), ranged from 1.2 to 2.60 ppm in the kidney tissues of the cows.

The above cited practices render the D.G.S. to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Food, Drug, and Cosmetic Act (FD&C Act) for causing illegal tissue residues in animals offered for slaughter as human food and Section 501(a)(5) in that it is deemed unsafe within the meaning of Section 512 of the FD&C Act. Section 512 deems a new animal drug unsafe unless an FDA approved application is in effect and the drug, its labeling, and use conform to the approved application.

The D.G.S. made by your clinic contains Gentamicin, which is not approved for oral or injectable use in cattle. Therefore, there is no tolerance for the presence of this drug in edible bovine tissue. The presence of Gentamicin in the tissue of cattle renders the food from the animal adulterated within the meaning of Section 402(a)(2)(C)(ii) of the FD&C Act.

The Animal Medicinal Drug Use Clarification Act (AMDUCA) passed by Congress in October 1994 (21 U.S.C. 360.b) and Title 21, Code of Federal Regulations, Part 530 (21 CFR 530) allow extralabel 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, extralabel use is permitted on the lawful order of a licensed veterinarian, within the context of a valid veterinarian-client-patient relationship, and may not result in any residue that may present a risk to the public health. The decision to use a product in an extralabel manner may not be made by a lay person. A copy of 21 CFR 530 and FDA Compliance Policy Guide, Section 608.400, are enclosed.

The above is not intended to be an all-inclusive list of the violations found at your facility. You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action being taken without further notice, such as injunction or prosecution.

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Please notify this office in writing, within 15 days of receipt of this letter, of each step that has been taken or will be taken to correct the violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe in which correction will be achieved.

Your response should be directed to the attention of Rosalie Bucey, Compliance Officer, at the above listed address.

Sincerely,



Lee Bowers
Director, Baltimore District

Enclosures: 2