



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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60 8th Street, N.E.
Atlanta, Georgia 30309

December 14, 2001

VIA FEDERAL EXPRESS

WARNING LETTER
(02-ATL-15)

Dr. Rhodnick B. Lowe
Rowan Animal Clinic
4155 Statesville Blvd.
Salisbury, North Carolina 28147

Dear Dr. Lowe:

A tissue residue investigation conducted by Investigator Richard L. Garcia in April 2001, confirmed that your actions caused an animal to be offered for sale for slaughter as food, in violation of the Federal Food, Drug, and Cosmetic Act (the Act). The animal was adulterated food within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Act.

On or about September 29, 2000, [REDACTED] sold a cow, identified with tag #55AA8082 and as USDA laboratory report number 413801, for slaughter as human food at [REDACTED]. The United States Department of Agriculture (USDA)/Food Safety and Inspection Service (FSIS) analysis of tissue collected from that animal disclosed the presence of the drug phenylbutazone in the kidney tissue. Phenylbutazone is not approved for use in dairy cattle. Use of this drug contrary to the approved conditions of use may only be done when a veterinarian is involved in the decision based on a valid veterinarian/client/patient relationship, no residue occurs, and other conditions described in Title 21, Code of Federal Regulations (21 CFR), Part 530, have been met.

There is no allowable tolerance established for residues of phenylbutazone in the edible tissues of cattle (21 CFR, Section 520.1720). The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you had injected phenylbutazone into the cow due to lameness. You also prescribed tablets of phenylbutazone to be administered to this cow by [REDACTED]. You further advised [REDACTED] that the withdrawal period for this drug in the treated animal was ten days. On April 10, 2001, you advised Investigator Garcia that this withdrawal period was in error and should have been fourteen days. Your reference for this was an article entitled "Extralabel Drug Use and Withdrawal Times in Dairy Cattle" in [REDACTED]. A recent review of safety data by the Center for

Veterinary Medicine indicated that the routine withdrawal time for phenylbutazone is approximately 45 days. FDA has significant concern over phenylbutazone residues in edible tissues. Available literature suggests the potential carcinogenicity of this drug as well as other serious toxicological findings including nephrotoxicity, aplastic anemia, and reproductive/developmental disorders.

Our investigation revealed that you had caused this animal to be treated and held under conditions that would cause the medicated animal bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

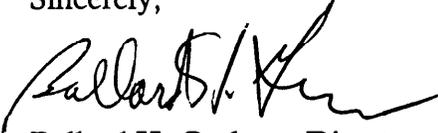
You are adulterating the [REDACTED] Phenylbutazone drug that the [REDACTED] farm used on cattle, within the meaning of Section 501(a)(5), when the drug was not used in conformance with its approved labeling. Your use of the drug in a species for which it is not approved causes the drug to be unsafe.

The above-identified violations are not intended to be an all-inclusive list of deficiencies at the dairy. You should take prompt action to correct the above and to establish procedures whereby such violations do not recur. Failure to do so may result in enforcement action being initiated by the FDA without further notice such as seizure and/or injunction.

You should be aware that it is not necessary for you to have personally shipped 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.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented. Your reply should be sent to the attention of Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely,



Ballard H. Graham, Director
Atlanta District