



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

January 14, 2000

2000-DAL-WL-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. Dan B. McWhorter, President
Mc6 Cattle Feeders, Inc.
P.O. Box 310
Hereford, Texas 79045

Dear Mr. McWhorter:

An investigation at your feed lot located at Hereford, Texas, conducted by our investigator on September 9, 1999, confirmed that you offered an animal for slaughter as food in violation of Sections 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you caused an animal drug, sulfadimethoxine, to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about July 8, 1999, you sold a cow, identified with ear tag number 537 3892, for slaughter as human food to [REDACTED], Inc., [REDACTED], Texas. USDA analysis of tissue samples collected from that animal identified the presence of 0.12 ppm sulfadimethoxine in the muscle. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle (Title 21, Code of Federal Regulations, 556.640). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that drugs are used according to the directions contained on the label or labeling and for assuring that animals medicated by your employees have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.

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Additionally, treatment records for animals fail to indicate the route of administration of the drug. Food from animals held under such condition is adulterated.

According to treatment records, the cow slaughtered on July 8, 1999 was treated with 45 ml doses of sulfadimethoxine 40% injection each day on June 29, and 30, 1999, and July 1, 1999. The labeled dosage for this drug for a cow weighing approximately 885 pounds at the time of treatment, would be 55.3 ml as an initial dose, and 27.6 ml every 24 hours thereafter. At the labeled dosage, the withdrawal time would be 5 days. Because the labeled dosage was exceeded, the withdrawal time should have been extended by consulting with a veterinarian to determine an appropriate withdrawal time.

You have adulterated the drug sulfadimethoxine within the meaning of Section 501(a)(5) when you and your employees fail to use the drug in conformance with its approved labeling. Your use of the drug without following the labeled dosage instructions causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

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

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was 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 notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

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Your reply should be directed to the Food and Drug Administration, Attention:
Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,

A handwritten signature in cursive script, appearing to read "Sylvain G. Gatt".

for Michael A. Chappell
District Director
Dallas District