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Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

Certified/Return Receipt Requested

March 1, 1999

WARNING LETTER

Mr. Ron Calfe, Owner
C Bar D Cattle Company
2108 200th Street
Gravity, IA 50848

KAN #99-016

Dear Mr. Calfe:

An investigation at your feedlot operation located at Gravity, Iowa on October 5, 1998, by an inspector from the Iowa Department of Agriculture, confirmed that you delivered an animal for slaughter as human food in violation of Section 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act), and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about August 3 or 4, 1998, you delivered a beef heifer, owned by Melvin Laughery, Fontanelle, Iowa, identified by USDA laboratory report 341989 as tag number M.O. 39004103, for slaughter as human food at [REDACTED] USDA analysis of samples collected from that animal identified the presence of tilmicosin in kidney, liver and muscle tissues [10.6 parts per million (ppm), 4.0 ppm and 0.42 ppm, respectively]. A tolerance of 1.2 ppm in liver as the target tissue has been established for tilmicosin in edible beef tissues. The presence of this drug in edible tissue from this animal causes this food to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased 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 in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld for appropriate periods of time to permit the depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

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You may also be adulterating the drug "Micotil-300" brand of tilmicosin that your firm uses on beef cattle within the meaning of Section 501(a)(5) if you fail to use the drug in conformance with its approved labeling. Use of the drug without following the labeled withdrawal period causes the drug to be unsafe.

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

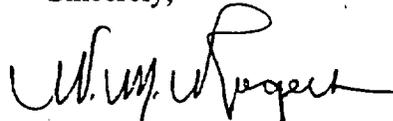
You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your food-producing animals.

It is not necessary for you personally to ship 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.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
District Director
Kansas City District