



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
M33471

January 13, 2000

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

Ref: 2000-DAL-WL-02

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

Mr. Gary Watson  
Gary Watson Dairy  
Route 4, Box 91C  
Stephenville, Texas 76401

Dear Mr. Watson:

An investigation at your dairy located at Stephenville, Texas, conducted by our investigator on July 15, 1999, and July 21, 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, Micotil (tilmicosin phosphate) to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about April 28, 1999, you delivered for sale at auction a cow identified with back tag #001 to [REDACTED]. That cow was offered for slaughter as human food at [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence 25 ppm of tilmicosin in the kidney, 19 ppm in the liver, and 2 ppm in the muscle. A tolerance of 1.2 ppm has been established for residues of tilmicosin in the edible tissues of cattle (Title 21, Code of Federal Regulations, Part 556.735). 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 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. Also, you lack a system 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. Additionally, treatment records do not identify the animal, the date medications were administered, the drug used, the dosage administered, and the pre-slaughter withdrawal times. Your practice of feeding colostrum from treated cows to calves intended for slaughter may cause potentially hazardous drug residues in the edible tissues of these calves. Food from animals held under such condition is adulterated.

You have adulterated the drug Micotil (tilmicosin phosphate) 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 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,



SOR Michael A. Chappell  
District Director  
Dallas District