



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M243617

March 2, 1999

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

99-DAL-WL-#09

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ezequiel "Ike" Tapia, Owner
Tapia Brothers Dairy Inc.
Route 2 - Box 193A
Miles, Texas 76861

Dear Mr. Tapia:

An investigation at your Tapia Dairy #2 operation located at Miles, Texas, conducted by our investigator on February 9 and 10, 1999 confirmed that you offered an animal for slaughter as food in violation of Sections 402(a)(2)(C)(ii), 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act. A List of Inspectional Observations, FDA-483, was issued to Mr. Edgar P. Tapia at the close of the inspection. A copy of the FDA-483 is enclosed.

On or about December 10, 1998, Mr. Edgar Tapia delivered a cow from Dairy #2 identified with back tag #6157, for slaughter as human food at San Angelo Packing Company, Inc., San Angelo, TX. USDA analysis of tissue samples collected from that animal identified the presence of 4.2 ppm sulfadimethoxine in the liver and 7.0 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:

1. You lack an adequate system for assuring that drugs are used according to the directions contained on the label, including adhering to the withdrawal times and other cautions stated on the label;

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2. You lack an adequate system for assuring proper training of personnel who administer drugs; that they adhere to the labeled directions and withdrawal times, and assuring controlled access to drugs by only trained personnel.
3. Your medication and treatment records fail to document each treated animal with the date of treatment, drug used, dosage administered and route of administration, and pre-slaughter withdrawal times.
4. You lack an adequate system for reviewing treatment records for adherence to withdrawal times prior to offering an animal for slaughter for food. Your system should include a method for withholding animals from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.
5. You lack an adequate system for identifying and segregating replacement heifers that have been medicated or may have been medicated and purchased from a producer.

Food from animals held under such condition is adulterated.

The cow slaughtered on December 10, 1998, appears to have been treated with sulfadimethoxine 40% injection within five (5) days prior to slaughter. You may have adulterated the drug sulfadimethoxine for injection within the meaning of Section 501(a)(5) when you failed to use the drug in conformance with its approved labeling. Your use of the drug without following the labeled withdrawal period (5 days) causes the drug to be unsafe to use. Additionally, the animal delivered for slaughter was not listed in your hospital pen records, and no record of its treatment was made.

On April 14, 1998, an investigator from the Texas Department of Health visited your Tapia Dairy #1 after a cull dairy cow was delivered to San Angelo Packing, San Angelo, Texas on February 23, 1998. USDA analysis of tissue samples collected from that animal identified the presence of 0.35 ppm penicillin in the liver, 0.29 ppm penicillin in the muscle tissue, and 0.60 ppm penicillin in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle (Title 21, Code of Federal Regulations, 556.510). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Additionally, FDA has brought similar violations to your attention in the past. On July 23, 1996, this office issued you a Warning Letter, 96-DAL-WL-#18, which identified many of these same violations.

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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 at any of your food producing facilities. 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.

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

Sincerely,



Joseph R. Baca
Dallas District Director

Enclosure: FDA-483

cc: Dr. J. Dennis Reed, D.V.M.
Dublin Veterinary Clinic
Route 5, Box 38
Dublin, Texas 76446

JRB:RRR:jab

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bcc: FF/LF/WLF/RF's

HFV-236

HFR-SW1

HFR-SW150

HFR-SW16 (Be aware of possible drug residues in milk.)

HFA-224

HFC-210 (1648648)

HFI-35 (thru CO)

Ed Edmiston (Residue Monitor)

USDA/Dr. Alan Knox, Acting District Manager

TDH (Dan Sowards)

No program required

Reviewed: AK 3.1.99