



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

d1513 b

November 19, 1996

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

Ref: 97-DAL-WL-05

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Charles A. Brown, Co-Owner
and Mr. Jon D. Brown, Co-Owner
J & K Cattle Company
P.O. Box 595
Chickasha, Oklahoma 73023

Dear Messrs. Brown:

An investigation of your cattle buying/raising operation, conducted May 28, 1996 and June 18, 1996, confirmed that you offered an animal for sale for slaughter as food in violations of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, and you caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act.

Our investigation 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 animals treated only with drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you or your employees have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

Further, our investigation found that you or an employee of your firm medicated a red cow, tag 73GX1343, by administering Terra-Vet 100 (oxytetracycline 100mg/ml) and did not adhere to the withdrawal time of twenty two days (22) days as required by the label. Instead, the medicated animal was offered for slaughter three (3) days after being medicated. Your use of this drug in a manner not in conformance with its approved labeling causes the drug to be adulterated within the meaning of Section 501(1)(5) of the Act.

You are adulterating the drug, Gentamicin Sulfate Solution that your firm uses on cattle within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved

Letter to Mr. Charles A. Brown and Mr. Jon D. Brown
November 19, 1996
page 2

labeling. Your use of the drug in a species for which it is not approved, causes the drug to be unsafe to use. Your animal medication cabinet also contains Spectam Solution (spectinomycin) labeled for use in turkey poults and newly hatched chicks and Spectam Scour-Halt oral solution (spectinomycin) labeled for use in pigs.

The above is not intended to be an all-inclusive list of violations. As producers 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.

As producers, you should take precautions such as:

1. controlling access of medications to employees authorized to administer drugs according to labeled directions, and record the administration of these drugs;
2. if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should take prompt action to correct the above violations and to establish procedures whereby by 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 may have caused the adulteration of an animal that was sold 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 being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 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.

Letter to Mr. Charles A. Brown and Mr. Jon D. Brown
November 19, 1996
page 3

Your reply should be directed to the attention of Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely yours,

Darryl E. Brown
Darryl E. Brown
Acting District Director

cc: 