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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204 6101

February 13, 1997

Ref: 97-DAL-WL-16

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Walter J. Klutts
Rt. 2, Box 232
Okemah, Oklahoma 74859

Dear Mr. Klutts:

An investigation of your cattle buying/selling operation on January 22, 1997, by investigators of the Food and Drug Administration (FDA) confirmed that you repeatedly offer animals for sale for slaughter as food in violation of Section 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). A food is adulterated if it bears or contains a new animal drug (or conversion product thereof) which is unsafe within the meaning of Section 512 of the Act (Section 402(a)(2)(D)). Additionally, you have caused a medicated animal feed containing a new animal drug to become adulterated within the meaning of Section 501(a)(6) of the Act.

On October 22, 1996, you delivered a spotted steer, identified with back tags #73CE8520 and #95099 for slaughter as human food at [REDACTED]. USDA analysis (Laboratory Report #847376) of tissue samples collected from this animal identified the presence of sulfamethazine at a level of 0.38 ppm in liver tissue and 0.25 ppm in muscle. A tolerance of 0.1 ppm has been established for residues of sulfamethazine in the edible tissues of cattle (Title 21 Code of Federal Regulations 556.670). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation found that you purchased the spotted steer on October 12, 1996, at [REDACTED] using your buyer identification code of [REDACTED]. You identify animals purchased under the code [REDACTED] as "animals in bad or severe condition, needing quick attention, or emergency care". You advised the FDA investigators that neither records available at the stockyard, nor records of individuals offering animals for sale are adequate to determine if an animal has been medicated. You made no attempt to determine the identification of the seller of the animal, or to determine if the animal in poor condition had been medicated.

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Additionally, 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 identifying medicated animals and assuring that animals treated with drugs or medicated feeds at your firm are appropriately withdrawn from the drugs prior to marketing animals for slaughter. Food from animals held under such conditions are adulterated within the meaning of Section 402(a)(4).

You held and fed the spotted steer at your firm from October 12, 1996, until delivered for slaughter on October 22, 1996. You confirmed to the investigators that, although you do not maintain records of administration of drugs or medicated feed to your animals or segregate treated animals, it is your routine practice to feed an animal the size and condition of the spotted steer a preconditioning ration PURINA PRECONDITIONING/RECEIVING CHOW CTSM (Chlortetracycline 70gm/ton and Sulfamethazine 0.0077%) on a free choice basis as a sole ration. You provided a label for this ration bearing statement "WARNING: Discontinue 7 days prior to slaughter." You confirmed the spotted steer was likely fed this ration. Investigators documented your receipt of a new delivery of this ration on October 15, 1996.

You have adulterated the medicated PURINA PRECONDITIONING/RECEIVING CHOW within the meaning of Section 501(a)(6) of the Act when you fail to use the feed containing a new animal drug in conformance with its approved labeling. Your use of the medicated feed without following the required withdrawal period (7 days) causes the feed to be unsafe within the meaning of Section 512(a)(2)(C).

The Food and Drug Administration (FDA) has received copies of USDA letters issued to you reporting a total of seven (7) tissue residues showing violative drug levels of sulfamethazine, streptomycin, erythromycin, chlortetracycline, and oxytetracycline since January 12, 1989. Four (4) of these residues occurred in the past three (3) years. Three (3) previous FDA inspections were conducted in follow-up to these residue reports. An FDA-483 List of Inspectional (observations was issued and discussed with you at the completion of each inspection. The FDA-483 described those conditions at your firm that may contribute to your firm's adulteration or the causing of the adulteration of animal tissue offered for slaughter. A Warning Letter (94-10A1-WL-#54) was issued to you from this office on August 11, 1994. I have attached copies of the referenced Warning Letter and Forms FDA-483.

Although the above warnings have been provided for violations of the Act, you continue to purchase at a significantly reduced price sick and lame animals and deliver these same animals for slaughter for food resulting in violative residues. You carry on these activities without any assurance, nor do you make any attempt to gain the assurances from the sellers, that the animals purchased by you and offered for slaughter have not been medicated requiring withdrawal for depletion of unsafe residues prior to shipment to the slaughter facility.

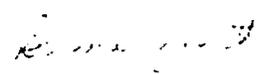
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As a buyer and dealer of animals which are offered into interstate commerce for use as food, you are responsible for assuring that your overall operation and the food you distribute are in compliance with the law. In view of your failure to correct the continuing violations resulting in the adulteration of food, and in an attempt to assure that consumers are not subjected to consumption of violative drug residues in beef tissue, we recommend that you meet with representatives of the Dallas District Office. Our main objective of this meeting is to assure correction to the ongoing violations and identify corrective actions to be taken by you to assure your firm's compliance.

We request that you notify this office in writing within fifteen (15) working days of your receipt of this letter, stating the specific steps you have taken to correct the noted deficiencies and the date you wish to meet with representatives of the FDA Dallas District Office. You should include in your response any documents supporting corrective actions you have taken at your firm. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You may address your response to James R. Lahar, Compliance Officer at the above letterhead address, 214/655-5318, ext. 333.

Sincerely yours,


Joseph R. Baca
Dallas District Director

Enclosures:

JRB:JRL:jab