



DEPARTMENT OF HEALTH & HUMAN SERVICES

G4312d

Food and Drug Administration

Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3145

September 18, 2003

Ref: 2003-DAL-WL-21

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

**WARNING LETTER**

Mr. Keith E. Lauer, Owner  
R&K Livestock  
519 North 2<sup>nd</sup> Street  
Texhoma, Oklahoma 73949

Dear Mr. Lauer:

An inspection of your cattle buyer/dealer operation located in Texhoma, Oklahoma, by Food and Drug Administration investigators on July 14, 2003, confirmed that you repeatedly offer animals for sale 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). 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)(C)(ii)].

On June 26, 2002 you delivered a cow, ear tag number [REDACTED] for slaughter as human food at [REDACTED] USDA plant number [REDACTED] USDA analysis (Laboratory Report #439330) of tissue samples collected from this animal identified the presence of oxytetracycline at 19.91 ppm in the kidney and 4.39 ppm in the muscle. A tolerance of 12.00 ppm and 2.00 ppm has been established for residues of oxytetracycline in the kidney and muscle respectively, for cattle (Title 21 CFR Section 556.500). The presence of this drug at a level exceeding the tolerance in edible tissue from this animal causes the food to be adulterated.

On October 23, 2002 you delivered a cow, back tag number 548, for slaughter as human food at [REDACTED] USDA plant number [REDACTED] USDA analysis (Laboratory Report #399510) of tissue samples collected from this animal

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identified the presence of penicillin at 0.09 ppm in the liver and 0.37 ppm in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in uncooked edible tissues of cattle (Title 21 CFR Section 556.510). The presence of this drug at a level exceeding the tolerance in edible tissue from this animal causes the food to be adulterated.

On November 6, 2002 you delivered a cow, ear tag number [REDACTED] for slaughter as human food at [REDACTED] USDA plant number [REDACTED] USDA analysis (Laboratory Report #447754) of tissue samples collected from this animal identified the presence of penicillin at 0.25 ppm in the liver and 5.56 ppm in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in uncooked edible tissues of cattle (Title 21 CFR Section 556.510). The presence of this drug at a level exceeding the tolerance in edible tissue from this animal causes the food to be adulterated.

On February 12, 2003 you delivered a cow, ear tag number 6371, for slaughter as human food at [REDACTED] USDA plant number [REDACTED] USDA analysis (Laboratory Report #447761) of tissue samples collected from this animal identified the presence of penicillin at 0.16 ppm in the liver and 0.86 ppm in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in uncooked edible tissues of cattle (Title 21 CFR Section 556.510). USDA also confirmed the presence of sulfadimethoxine at 0.43 ppm in the liver and 0.67 ppm in the muscle. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in uncooked edible tissues of cattle (Title 21 CFR Section 556.640). The presence of penicillin and sulfadimethoxine at levels exceeding the tolerance for each in edible tissue from this animal causes the food to be adulterated.

On June 9, 2003 you delivered a cow, ear tag number [REDACTED] for slaughter as human food at [REDACTED] USDA plant number [REDACTED] USDA analysis (Laboratory Report #447772) of tissue samples collected from this animal identified the presence of penicillin at 0.17 ppm in the liver, 0.73 ppm in the kidney, and 0.83 ppm in the muscle. A tolerance of 0.05 ppm has been established for residues of penicillin in uncooked edible tissues of cattle (Title 21 CFR Section 556.510). The presence of this drug at levels exceeding the tolerance in edible tissue from this animal causes the food to be adulterated.

It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animal. As such you share the responsibility for violating the Federal Food, Drug and Cosmetic

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Act. To avoid future illegal residue violations you should take the following precautions:

- Your firm should implement a system to identify the animals you purchase with records to establish traceability to the source of the animal. Your documents do not include and should include identification of individual cows by tag number or other identifier to allow traceability to the source of the animal when multiple purchases and/or deliveries are made in one day.
- Your firm should implement a system to determine from the source of the animal whether the animal has been medicated, with which drug(s), the dosage, the route of administration and the remaining withdrawal period. If medicated, the animal should be withheld from slaughter to deplete drug residue levels in edible tissues of the animal. Your current system does not include and should include documentation of these assurances for each animal at the time of purchase.
- Additionally, you continue to do business with sources who have repeatedly provided false assurances of the medication status of animals you purchase. Continuing to do business with these firms with knowledge that the information they provide is false or inaccurate causes you to be responsible for residue violations that occur as a result of animals purchased and offered for food from these sources.

We received the letter, dated July 18, 2003, that you sent in response to the inspection of your firm. In your letter you specify that your corrective action is to add 5-10 days to the withdrawal time for medicated animals. This correction is not adequate without your determination and documentation of the treatment regimen. The documentation should include the drug used, dosage, route of administration and the remaining withdrawal period determined by the labeling or a licensed veterinarian when the drug is used contrary to the labeling.

In your letter you additionally provide copies of signed documents titled "Farmer/Rancher/Dealer Certification of FDA Compliance". These documents are blanket statements from your cattle suppliers that the animals they supply to you have been handled in a manner to prevent a pharmaceutical or agricultural chemical residue violation. These blanket statements of compliance are inadequate. You have the responsibility to assure that every animal you purchase and offer for slaughter for human food is free of drug residues and to include documentation of the medication status at the time of purchase for each animal.

The above is not intended to be an all-inclusive list of violations. You should take prompt action to correct these violations and to establish procedures to prevent

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their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office, in writing, within fifteen (15) working days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to Reynaldo R. Rodriguez, Jr., Director, Compliance Branch, at the above letterhead address.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael A. Chappell". The signature is fluid and cursive, with a large initial "M" and "C".

Michael A. Chappell  
Dallas District Director

MAC:rrr:slk:jab