



October 2, 2003

Ref: 2004-DAL-WL- 01

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Fred M. Cox, Jr., Owner
Fred M. (Morrison) Cox, Jr. Farm
7203 East 350 Road
Talala, Oklahoma 74080

Dear Mr. Cox:

An inspection by an investigator of the Food and Drug Administration at your cow/calf operation at the above location on March 11, 2003, confirmed that you offered a bull 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). A food is adulterated if it bears or contains a new animal drug (or conversion product thereof) which is unsafe. The inspection also shows that you have caused new animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act.

On December 16, 2002, you delivered a bull for slaughter as human food at [REDACTED] Establishment Number [REDACTED]. USDA analysis of a liver tissue sample collected from the bull, by the Oklahoma Department of Agriculture Inspector, identified the presence of ivermectin in edible tissue at the level of 252.7 parts per billion (ppb). A tolerance level of 100 ppb has been established for residues of ivermectin in the liver tissue of cattle [Title 21, Code of Federal Regulations (CFR) 556.344]. The presence of ivermectin at a level above the tolerance in the edible tissue of the animal causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act.

During the current inspection of your farm, our investigator documented your statement confirming that you administered Merial brand of Ivomec Plus (ivermectin and clorsulon) injectable wormer subcutaneously to the bull. You indicated the Ivomec Plus was received from [REDACTED]. The investigator verified your purchase of 2/500 ml units of the ivermectin drug labeled in part "***Ivomec Plus, Lot No.

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LBC0590, ** Made in the Netherlands** Merial Limited, Iselin, NJ, USA**" on October 15, 2002. The purchase is covered by [REDACTED] Sales Ticket dated 10/15/02.

A food is also adulterated if it has been held under insanitary conditions whereby it may have been rendered injurious to health. Our investigator found that you hold animals under conditions that could allow medicated animals bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for assuring that drugs are administered in a manner that is not contrary to the directions contained in the product labeling and for assuring that medicated animals have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated under Section 402(a)(4) of the Act.

You are also responsible for adulterating the Ivomec Plus drug product used in your operation to medicate the bull. A drug is unsafe within the meaning of Section 512(a)(1) of the Act if its use does not conform with its approved application. The label for Ivomec Plus brand of ivermectin specifically directs that the maximum dose per injection site is 10 ml. Our investigator documented your statement that you had subcutaneously injected 15 ml of Ivomec Plus into a single injection site in the bull offered for slaughter on December 16, 2002, based on the animal's weight of approximately 1600 lbs. Your failure to administer the drug as directed rendered the drug "unsafe" under section 512(a)(1) of the Act and therefore adulterated under section 501(a)(5) of the Act.

The extralabel use of veterinary drugs is only authorized by or under the direction of a licensed veterinarian having a valid veterinarian-client-patient relationship.

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 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 receipt of this letter, of the specific steps taken to correct the noted violations. Include the documentation of any corrections and an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason and the date when corrections will be completed.

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Your reply should be sent to James R. Lahar, Compliance Officer, at the above letterhead address.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Michael A. Chappell". The signature is fluid and cursive, with a large initial "M" and a long, sweeping tail that loops back under the name.

Michael A. Chappell
District Director

MAC:JRL