

DEPARTMENT OF HEALTH & HUMAN SERVICES

HFE-35
Public Health Service
D1235B

March 4, 1997

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

WARNING LETTER
CIN-WL-97-292

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Leroy & Pat Baker
102 Buckeye Street
Sugarcreek, Ohio 44681

Dear Mr. & Mrs. Baker:

FDA investigators conducted investigations during November, December 1996 and February 1997 at your cattle buying dealership, at [REDACTED] and at the [REDACTED] Auction. These investigations showed you caused a bob veal calf containing illegal levels of drug residues to be shipped in interstate commerce and to be sold at auction in a manner which resulted in the calf being purchased for slaughter by Martin Yoder for Atlantic Veal and Lamb, Inc. of Brooklyn, NY. This is in violation of 21 U.S.C. 331(a), 342(a)(2)(D) and 342(a)(4).

The calf bearing back tag 31NK 2275 was slaughtered at Fanchers Meats in Shinnston, WV, sampled and found to contain 11 parts per million (ppm) oxytetracycline in the liver and 6.1 ppm oxytetracycline in the kidney. The legal limit for oxytetracycline in liver is now set at 6 ppm and 12 ppm in the kidney of calves. While this has recently been raised from 0.1 ppm in the edible tissues of calves, the levels found in calf 31NK 2275 is well above the legal limit.

The investigation showed that you had not maintained records which provided identification trace back capability to the original producer who sold the animals through Mammoth Cave Auction. This was caused by removing the back tags and not being able to identify the calves by some reliable means when the new back tags were applied at [REDACTED] Auction.

Further there was no evidence that any means of determining the drug residue legal status of the bob veal calf was exercised by the [REDACTED] Auction or [REDACTED] Auction at the time of this purchase and sale.

The above is not intended as an all-inclusive list of violations. As a buyer and shipper of animals which are offered for use as food, you are responsible for assuring that your overall operations and the food you distribute are in compliance with the law. Since the occurrence of this violation we have entered into the Ask and Tell program at your Sugarcreek Auction Market and you have a better understanding of the need to assure the drug residue legal status of calves you purchase with a view toward sale for slaughter.

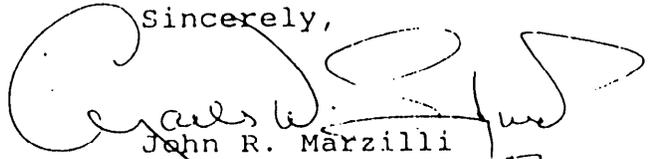
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You should take prompt action to assure your procedures prevent a recurrence in the future. Failure to promptly correct the conditions may result in regulatory action without further notice; such as an injunction.

You should notify this office in writing within 15 working days of receipt of this letter stating the specific steps you have taken to assure this violation will not recur.

Your reply should be sent to the Food and Drug Administration, Cincinnati District Office, 1141 Central Parkway, Cincinnati, Ohio 45202, ATTN: Leonard J. Farr, Compliance Officer.

Sincerely,

A handwritten signature in black ink, appearing to read "John R. Marzilli". The signature is written in a cursive style with a large initial "J" and "M".

John R. Marzilli
District Director
Cincinnati District Office

LJF/clc