



DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI 3003537689

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Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5707

02-BLT-15

February 11, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Paul H. Lambert, President
Lambert Farms, Incorporated
10223 Lenhart Road
Frederick, Maryland 21701

Dear Mr. Lambert,

An inspection of your dairy operation located in Frederick, Maryland, by the Food and Drug Administration on January 4-14, 2002, confirmed that a calf you offered for sale for slaughter as food, was in violation of Section 402 (a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about December 4, 2000, you sold a Bob veal bull calf, identified with tag [REDACTED] for slaughter as human food at [REDACTED]. USDA/FSIS analysis of tissues collected from that animal disclosed the presence of 33.38 ppm of [REDACTED]. The presence of neomycin in the edible tissues of this Bob veal calf causes the food to be adulterated, since no tolerance has been established for use of this drug in veal calves. Introducing adulterated food into interstate commerce is a violation of Section 301(a) of the Act.

Our investigation also 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:

1. You lack an adequate system for assuring that animals have been treated only with drugs that have been approved for use in those species.
2. You lack a system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling.
3. You lack a system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues.

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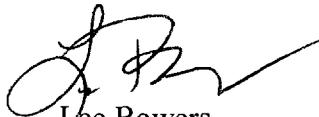
Food from animals held under such conditions is adulterated. You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in FDA taking regulatory action without further notice to you.

In addition, you should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Please notify this office in a detailed written response within 15 working days of receipt of this letter, of the steps you have taken to correct the noted violations and to prevent recurrence. If corrective action can not be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

You should direct your response and questions to the Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215-3215, to the attention of Vinetta Howard-King, Compliance Officer. Ms. Howard-King can be contacted at telephone number (410) 779-5454 x 413.

Sincerely,



Lee Bowers
Director, Baltimore District

Cc:

