



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
TFC-35 m3916n

60 8th Street, N.E.
Atlanta, Georgia 30309

June 9, 2000

VIA FEDERAL EXPRESS

Bradley A. Johnston
President
Taproot Dairy LLC
248 Butler Bridge Rd.
Fletcher, North Carolina 28732

WARNING LETTER
(ATL 45-00)

Dear Mr. Johnston:

An inspection of your dairy operation located in Fletcher, North Carolina, conducted by our investigator on March 14, 2000, confirmed that two cows sold by you on or about 7/22/99 and 9/4/99, for slaughter for human food to [REDACTED] was in violation of Section 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

USDA/FSIS analysis of tissues collected from the two animals disclosed the presence of neomycin in the kidneys. Neomycin was found in the kidney at 154.00 ppm in one cow and at 99.00 ppm in the second cow. A tolerance of 7.2 ppm has been established of residues of neomycin in the edible tissues of cattle (Title 21 Code of Federal Regulations Section 556.430.) The presence of this drug in edible tissue from these animals causes the food to be adulterated.

Our investigation also found that you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling, and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

You are adulterating the drug Biosol Liquid Neomycin Sulfate that your firm uses on cows within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling.

The violations listed above are not intended to be an all inclusive list. It is your responsibility to assure that your operations are in compliance with the law. To avoid future illegal residue violations, you should take precautions such as implementing a system to withhold the animal,

if it has been medicated, from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

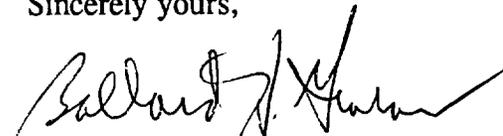
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure, and/or injunction.

You should be aware that it is not necessary for you to have personally shipped an animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Sheryl R. Cruse, Compliance Officer, at the above noted address.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District

cc:

