



January 29, 2003

VIA FEDERAL EXPRESS

Bradley A. Johnston, Owner
Taproot Dairy LLC
248 Butler Bridge Road
Fletcher, NC 28732

Warning Letter
03-ATL-11

Dear Mr. Johnston:

An investigation at your dairy farm located at Fletcher, North Carolina, conducted by our investigators on December 18 & 20, 2002, confirmed that in October 2002 you offered a cow for sale for slaughter for human food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The investigation also revealed you caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about October 22, 2002, you sold a cow, identified with back tag number 56HB8773¹, to [REDACTED], for slaughter as human food. USDA analysis of tissue samples collected from this cow identified the presence of the drug penicillin at a level of 0.34 part per million (ppm) in the kidneys and 0.19 ppm in the liver. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle (Title 21, Code of Federal Regulations, Section 556.510). The presence of this drug, at levels above the tolerance, in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also 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 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. As noted in the Form FDA 483, issued to you on December 20, 2002, you failed to follow labeled dosage amounts when administering the drug to the affected cow, and also failed to maintain treatment records for cow #1947, including dates

¹ The back tag number was assigned to the cow by [REDACTED] upon receipt.

of administration, dosage, drug and withdrawal times. Food from animals held under such conditions is adulterated under Section 402(a)(4) of the Act.

In addition, you caused the drug [REDACTED], containing penicillin G procaine, which your farm uses on dairy cows, to become adulterated within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its approved labeling. Your use of this drug in dairy cattle either at higher than labeled dosages or without following the labeled withdrawal period causes the drug to be unsafe to use.

The above-identified violations are not intended to be an all-inclusive list of deficiencies at your dairy farm. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

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 enforcement action being initiated by the FDA 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 adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing within fifteen (15) days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Carlos A. Bonnin, Compliance Officer, at the address noted in the letterhead.

Sincerely,



Mary H. Woleske, Director
Atlanta District