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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration  
158-15 Liberty Avenue  
Jamaica, NY 11433

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Earl Owens, Owner  
8541 La Rue Rd.  
Bath, NY 14810

February 26, 2003

File No.: NYK 2003-14

Dear Mr. Owens:

On January 15 and 16, 2003, U.S. Food and Drug Administration investigators conducted an inspection of your dairy farm located in Bath, New York. This inspection confirmed that in August 2002 you offered an animal for sale for food that was adulterated within the meaning of Sections 402 (a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed serious deviations from the regulations for Extralabel Drug Use in Animals (Title 21, Code of Federal Regulations, Part 530). These deviations caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act. You are also in violation of Section 301(h) of the Act in that you provided a false guaranty.

On or about August 20, 2002, you offered for sale a cow identified with ear tag 21ZCM5111 and farm tag 176 for slaughter as human food. The cow was sold to and slaughtered at [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of 0.15 parts per million (ppm) of penicillin in kidney tissue.

A tolerance of 0.05 ppm has been established for residues of penicillin in the uncooked edible tissues of cattle (Title 21 Code of Federal Regulations 556.510). The presence of this drug in excess of that tolerance in the kidney tissue of this animal caused the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about April 1, 2001 you provided [REDACTED] a signed Livestock Owner's Certificate. This certificate certified that none of the livestock delivered to [REDACTED], would be adulterated within the meaning of the Act and that none of the livestock would have an illegal level of drug residues. On or about August 20, 2002, you sold the above identified cow, adulterated with the above-discussed penicillin residue, to [REDACTED]

Our investigation also found that you hold animals on your farm under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you failed to maintain a drug inventory system.

Earl Owens  
Bath, NY 14810

Foods from animals held under such conditions are adulterated under Section 402(a)(4).

You also caused the drug Penicillin G Procaine, containing penicillin, to become adulterated within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with the labeling. Your extra label use of this drug at levels that exceeded the recommended dosage limits without the oversight of a veterinarian causes the drug to be unsafe for use.

You should not consider this an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action, without further notice. This may include seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact you caused the adulteration of an animal that was sold and 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 15 working days, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. Your response should be directed to Richard T. Trainor, Compliance Officer, at the following address: FDA, 300 Hamilton Ave., White Plains, New York 10601.

Sincerely,



Jerome G. Woyshner  
District Director