DEPARTMENT OF HEALTH & HUMAN SERVICES

94989d

Public Health Service

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

September 30, 2004

WARNING LETTER
2004-DT-08

Mr. Chris J. Parker, Co-Owner
Parker & Sons, LLC
10462 South 450 West
Silver Lake, Indiana 46982

Dear Mr. Parker:

On May 14-15, 2004, U.S. Food and Drug Administration investigators conducted an inspection at your farm located at 10462 South 450 West, Silver Lake, Indiana. This inspection confirmed that you offered an animal for sale for food that was adulterated within the meaning of Section 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). A food is adulterated under Section 402 (a)(2)(C)(ii) of the Act if it contains a new animal drug which is unsafe within the meaning of Section 512(a) of the Act.

On or about January 14, 2004, you offered for sale an adult dairy cow identified with low hip tag #8755 for slaughter as human food. This cow was sold to and slaughtered at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of [redacted] of gentamicin in [redacted] of gentamicin in [redacted] and the presence (amount not quantified) of gentamicin in muscle tissue.

Gentamicin is not approved for use in cattle and no tolerance has been established for residues of gentamicin in edible tissues of cattle. The presence of this drug in edible tissues of 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 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 lack a system for assuring animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues. For example, there are no records for the treatment of the above cow with gentamicin. Foods from animals held under such conditions are adulterated under Section 402 (a)(4).

You are also adulterating the drug gentamicin within the meaning of Section 501(a)(5) of the Act. You used this drug in cattle, a species for which it is not approved. Because your extra label use of gentamicin was not in compliance with 21 CFR Part 530, the drug is unsafe under Section 512(a) of the Act.

This is not 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, such as seizure and/or injunction.

We note that this in not the first residue associated with your farm. Since 1999, you offered for sale at least four other dairy cows and one bob veal calf for slaughter for human food. USDA analysis of tissue samples collected from these animals identified the presence of gentamicin in kidney tissue. There is no tolerance established for residues of gentamicin in edible tissues of cattle (21 C.F.R. 556.300).

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 that 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. Likewise, the fact that you caused the adulteration of a drug that had been sold 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 farm into compliance with the law. Your response should include each step you have taken or will take to prevent the recurrence of similar violations. 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. Your response should be directed to Judith Jankowski, Compliance Officer, at the Detroit District Office of the U.S. Food and Drug Administration, 300 River Place, Suite 5900, Detroit, MI 48207. Please include copies of any available documentation demonstrating that corrections have been made.

Sincerely your,

Joann M. Givens

Joann M. Givens
District Director
Detroit District Office