



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Kansas City District  
Southwest Region  
11630 West 80<sup>th</sup> Street  
Lenexa, Kansas 66214-3340  
Telephone: (913) 752-2100

August 5, 2003

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER**  
Ref. KAN 03-10

Mr. Tom R. Milius, President  
Wilson C. Milius, Inc.  
2231 270<sup>th</sup> St.  
Denver, IA 59622

Dear Mr. Milius:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a cow owned by your firm. As a follow-up to USDA's finding, our investigator performed an inspection of your operation on April 30, 2003. The inspection confirmed that you offered an animal for sale for slaughter as food, in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, and Cosmetic Act (Act), and that you may have caused an animal drug to become adulterated within the meaning of section 501(a)(5) of the Act.

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. A dairy cow owned by your firm and culled for slaughter for human food was found to contain illegal levels of a drug residue by the United States Department of Agriculture (USDA) testing.

On March 11, 2003, USDA - FSIS collected a sample which tested positive for the presence of gentamicin residues at 0.73 parts per million (ppm) in the kidney sample collected from a culled dairy cow identified with retain tag number 44793549, and USDA Sample Number 447330. There is no tolerance established for residues of gentamicin in cattle (21 Code of Federal Regulations (CFR) 556.300). The presence of this drug 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. A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions whereby . . . it may have been rendered injurious to health." As it applies in the case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues may enter the food supply.

In addition, you are adulterating the drug gentamicin that you use on cattle within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug contrary to the directions and without following labeled withdrawal periods causes the drugs to be unsafe to use.

This is not intended to be an all-inclusive list of violations. 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 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 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.

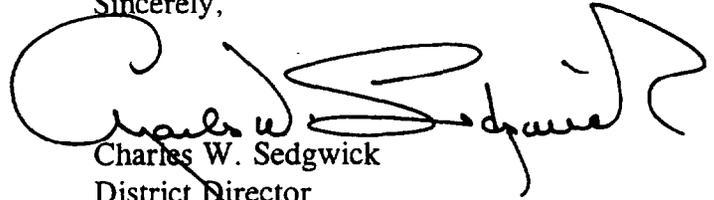
We note that this is not the first time an illegal drug residue has been found in a cow owned by you. On March 6, 2002, USDA - FSIS collected a sample which tested positive for the presence of penicillin residues at 0.14 parts per million (ppm) in the kidney, and 0.20 ppm in the liver of tissue samples collected from a culled dairy cow identified with retain tag number 43947005, and USDA Sample Number 423218. A tolerance is established for residues of penicillin at 0.05 ppm (negligible residues) in uncooked edible tissues of cattle (21 CFR 556.510).

You should notify our office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of

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any documentation demonstrating that corrections have been made. Please direct your reply to Nadine Nanko Johnson, Compliance Officer, at the address listed above.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is stylized with large, sweeping loops and a prominent initial "C".

Charles W. Sedgwick  
District Director  
Kansas City District