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Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 8, 2002

WARNING LETTER
KAN #2002-06

Brent J. Rus, Owner
Brent Rus Farm
3330 & 3287 Dogwood Avenue
Rock Valley, IA 51247

Dear Mr. Rus:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residues in a cow that originated from your cattle raising operation. As a follow-up to USDA's finding, our investigator performed an inspection of your operation located in Rock Valley, Iowa, on March 21 to 25, 2002. The inspection revealed serious violations of Section 402 and 501 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 that is unsafe within the meaning of Section 512. On/about February 12, 2002, you offered a cow, identified with back tag number 41 MN 4358 (USDA laboratory report number 442053), for slaughter as human food. USDA analysis of tissue samples collected from that cow identified the presence of the drugs penicillin in the kidney at 0.55 parts per million (ppm), gentamicin in the kidney at 6.09 ppm, and sulfamethazine in the muscle at 6.22 ppm. Presently, the tolerance level for penicillin and sulfamethazine in the edible tissues of cattle is 0.05 ppm and 0.1 ppm respectively. There is no tolerance for gentamicin in the edible tissues of cattle.

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 are likely to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those species; 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.

You are adulterating the drugs penicillin, gentamicin and sulfamethazine that you use on cattle within the meaning of Section 501(a)(5) when you fail to use the drugs in conformance with its approved labeling. Your use of the drugs in a species for which it is not approved, at a higher than labeled dosage, or without following labeled withdrawal periods, causes the drugs to be unsafe to use.

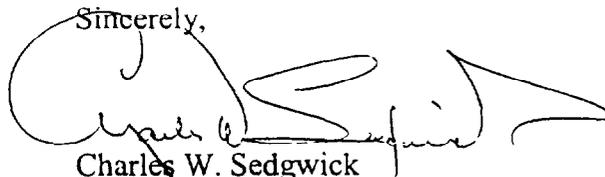
This is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

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.

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 any documentation demonstrating that corrections have been made. Please direct your reply to Clarence R. Pendleton, Compliance Officer, at the address listed above.

Sincerely,



Charles W. Sedgwick
District Director
Kansas City District

cc: Marion J. Rus, Owner
Marion Rus Farm
3283 Dogwood Avenue
Rock Valley, IA 51247