



93299 #

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis, MN 55401-1000
Telepl

June 3, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 32

Clyde J. Brunner
Co-Owner
Clyde Brunner Farm
4757 Algoma Road
New Franken, Wisconsin 54229

Dear Mr. Brunner:

On January 23 and 30, 2002, an investigator from the Food and Drug Administration (FDA) conducted an inspection at your dairy operation. That 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, Drug and Cosmetic Act (the Act).

On or about December 18, 2001, you sold a cow identified with back tag number 35ME3893 for slaughter as human food to  United States Department of Agriculture (USDA) analysis of tissue samples collected from that animal identified the presence of 1.36 ppm gentamicin. No tolerance has been established for residues of gentamicin in the edible tissues of cows. 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 found that you hold animals under conditions that are so inadequate that diseased animals and/or animals bearing potentially harmful drug residues are likely to enter the food supply. As noted in form FDA-483 issued to you on January 30, 2002, you did not maintain traceback records and failed to maintain drug treatment records for cows held on your farm. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

Page Two

Clyde J. Brunner
June 3, 2002

The above 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 ensuring that your operations and the foods you distribute are in compliance with the law.

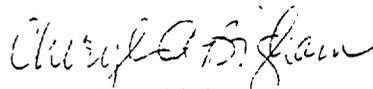
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not occur. Failure to do so may result in regulatory action (such as seizure or injunction) without further notice to you.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be held responsible for a violation of the Act. The fact that you offered an animal for sale that was ultimately sold to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your dairy operation into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. 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. Please include copies of any available documentation that corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,



Cheryl A. Bigham
Acting Director
Minneapolis District

TGP/ccl