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Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

August 21, 2000

## WARNING LETTER

### CERTIFIED MAIL RETURN RECEIPT REQUESTED

Refer to MIN 00 - 49

James W. Broderick  
Owner and Operator  
James Broderick Dairy Farm  
W9940 County Road P  
Pound, Wisconsin 54161

Dear Mr. Broderick:

On July 31, 2000, investigators from the Food and Drug Administration (FDA) and the Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP) conducted an investigation at your dairy farm located in Pound, WI. That investigation confirmed that you offered raw milk for sale in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about June 19 and 21, 2000, you sold raw milk for use as human food to \_\_\_\_\_ who subsequently sold the milk to \_\_\_\_\_  
\_\_\_\_\_ WDATCP testing found Sulfonamide drugs in a milk sample collected from \_\_\_\_\_ on June 19, 2000. Further testing by WDATCP on milk samples collected on June 21, 2000, including "patron" samples from your farm, found Sulfonamide drugs in the milk. FDA analysis of the milk samples collected on June 19, 2000, from \_\_\_\_\_ identified the presence of Sulfamethazine, a drug that is prohibited for use in dairy cattle.

Our investigation at your farm found practices whereby potentially harmful drug residues are likely to enter the food supply. You admitted to treating respiratory illnesses in your female dairy cattle with Sulfamethazine. Also, as noted in the form FDA-483 issued to you on July 31, 2000, you are not keeping records of medication of your dairy cows and calves to avoid drug residues in milk and meat. You lack an adequate system for assuring that your dairy cows have been treated only with drugs which have been approved for use and for assuring that drugs are used in a manner not contrary to the directions

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contained in the labeling. Milk from animals held under such conditions is adulterated.

You are adulterating the \_\_\_\_\_ brand of Sulfamethazine 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 on female dairy cattle and calves under one (1) month of age causes the drug to be unsafe. Extralabel use of Sulfamethazine is prohibited by 21 CFR 530.41 (copy enclosed).

The above is not intended to be an all-inclusive list of violations. As a milk producer, you are responsible for ensuring that your operations 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. Please tell us what you plan to do with Sulfamethazine drugs that are in your possession.

You should be aware that it is not necessary for you to personally ship adulterated milk in interstate commerce to be held responsible for a violation of the Act. The fact that you caused the adulteration of milk that was subsequently offered for sale 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 farm 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 date by which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

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

Sincerely,



Edwin S. Dee  
Acting Director  
Minneapolis District

TGP/ccl  
Enclosure: As directed