



Dad

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

**PURGED** RJK

January 17, 2001

**WARNING LETTER****CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 01 - 25

Dale Shulfer  
Shulfer Dairy  
2732 5-Corner Road  
Amherst Junction, Wisconsin 54407

Dear Mr. Shulfer:

An investigation conducted by our investigators at your dairy operation located at Amherst Junction, WI, on November 30, 2000, confirmed that you offered an animal 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 July 12, 2000, you sold a bob veal calf identified with back tag number 35 MM 1072 for slaughter as human food at *minneapolis*. This calf was slaughtered at *minneapolis* U.S. Department of Agriculture (USDA) analysis of tissue samples collected from that animal identified the presence of 4.41 parts per million (ppm) gentamicin in the liver and 210.74 ppm gentamicin in the kidney. A tolerance for gentamicin in the uncooked edible tissue of veal has not been established, therefore, no residue is permitted. The presence of this drug in edible tissue from this animal causes the food to be adulterated. A food is adulterated within the meaning of 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 of the Act.

A food is also adulterated within the meaning of 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 applied in this 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 possible harmful drug residues are likely to enter the food supply. For example, our investigators noted the following:

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1. You lack an adequate system for determining the medication status of animals you offer for slaughter.
2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
3. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their species or class.
4. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

In addition, you should also notify                      you are treating your animals with cephalixin benzathine, the active drug in                      and neomycin. Milk should be discarded for 72 hours after calving and the meat should be withheld from slaughter for 42 days if the animal has been treated with cephalixin benzathine. No time has been established for discarding milk from animals treated with neomycin.

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 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.

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 subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

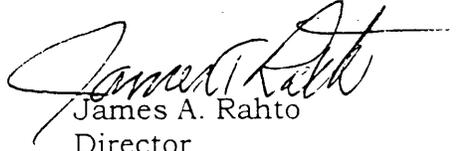
You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective 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 demonstrating that corrections have been made.

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

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

RPS/ccl

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Steve Steinhoff  
Wisconsin Department of Agriculture,  
Trade and Consumer Protection  
2811 Agriculture Drive, P.O. Box 8911  
Madison, WI 53708-8911