



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

December 28, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 18

Henk G.B. Kenkhuis
Owner
Hen-Lin Dairy
24425 St. Peters Road
Darlington, Wisconsin 53530

Dear Mr. Kenkhuis:

An investigation at your cattle operation located at Darlington, WI, conducted by our investigators on November 6, 2001, confirmed that you offered animals 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), and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about September 11 and again on September 24, 2001, you sold dairy cows identified with back tag numbers 35CR4722 and 35CR5853, for slaughter as human food at [redacted] U.S. Department of Agriculture (USDA) analysis of tissue samples collected from these animals identified the presence of sulfadimethoxine in both cows (7.42 ppm in the liver and 4.56 ppm in the muscle of cow 35CR4722, and 7.90 ppm in the liver and 2.90 ppm in the muscle of cow 35CS5853). A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle (Title 21, Code of Federal Regulations, Part 556.640). The presence of this drug in edible tissue from these animals cause the food to be adulterated.

In addition to our November 6, 2001, investigation at your cattle operation, USDA has reported finding illegal sulfadimethoxine residues in two additional dairy cows sold by you for slaughter as human food at [redacted]. These animals are identified with back tags 35CR5-929 and 35CR5-942. A copy of the letter from USDA/FSIS notifying you of these residues is attached.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely 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

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you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissue. Foods from animals held under such conditions are adulterated.

You are adulterating a  brand of sulfadimethoxine that your firm uses on dairy 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 sulfadimethoxine in dairy cattle either at higher than labeled dosages or without following the labeled withdrawal period causes the drug to be unsafe to use.

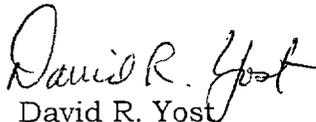
The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the foods you distribute are in compliance with the law. You should take prompt action to correct the above violations 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 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.

Your reply should be directed to Acting Compliance Officer Greg A. Abel at the address indicated on the letterhead.

Sincerely,



David R. Yost
Acting Director
Minneapolis District

GAA/ccl

Enclosure: USDA/FSIS to Hen-Lin Dairy, 11/16/01