



DEPARTMENT OF HEALTH AND HUMAN SERVICES

9/14/03
Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

November 14, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 07

Jack Hanke
Owner
Hanke Farms, Inc.
N6368 Willow Road
Sheboygan Falls, Wisconsin 53085

Dear Mr. Hanke:

On September 22, 2003, an investigator from the Food and Drug Administration (FDA) conducted an inspection at your dairy farm located in Sheboygan Falls, WI. That investigation revealed that your dairy farm caused an animal drug to be unsafe under Section 512(a) of the Federal Food, Drug and Cosmetic Act (the Act) and adulterated within the meaning of Section 501(a)(5) of the Act, because the drug was used in a manner that does not conform with its approved use or the extralabel use regulations at 21 C.F.R. Part 530 (enclosed).

On or about May 6, 2003, you sold a dairy cow (eartag #1184, backtag #35HW2176) for slaughter as human food to   U.S. Department of Agriculture (USDA) analysis of tissue samples collected from this cow identified the presence of sulfadimethoxine at 7.83 ppm in the liver and 6.21 ppm in muscle tissue. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle, 21 C.F.R. § 556.640 (copy enclosed).

You adulterated sulfadimethoxine within the meaning of Section 501(a)(5) when you failed to use the drug in conformance with the approved conditions of use or the extralabel use regulations at 21 C.F.R. Part 530. According to your "COW HEALTH & BREEDING RECORD," you treated cow number 1184 with sulfadimethoxine on May 1, 2003. The cow was then culled and slaughtered on May 6, 2003. You failed to follow the seven day withdrawal period that is specified in the labeling for sulfadimethoxine. Because your use of sulfadimethoxine did not conform to the

Page Two

Jack Hanke
November 14, 2003

drug's approved conditions of use or the extralabel use regulations at 21 C.F.R. Part 530, the drug is unsafe under Section 512(a) of the Act. As a result, your use of this drug caused it to be adulterated within the meaning of Section 501(a)(5) of the Act.

It is not necessary for you to personally ship an adulterated drug in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of a drug that was sold in interstate commerce is sufficient to hold you responsible for the violation.

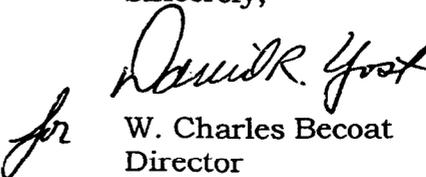
Our September 22, 2003, inspection also covered a July 7, 2003, illegal residue of gentamicin (0.19 ppm in kidney) in a dairy cow (backtag #35HW2856) that you offered for slaughter to  Gentamicin is not approved for use in dairy cattle. In your reply to this Warning Letter, please verify that you no longer use gentamicin in your dairy operation.

The above is not intended to be an all-inclusive list of violations. For example, our investigation found deficiencies in your recordkeeping practices. See the Form FDA-483 that was issued to you on September 22, 2003, for details. 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.

Please notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm 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 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,


W. Charles Becoat
Director
Minneapolis District