



PURGED

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

September 23, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 67

John A. Schoenberg
Owner
Schoenberg Dairy
30614 - 353rd Avenue
Melrose, Minnesota 56352

Dear Mr. Schoenberg:

A recent investigation conducted by our investigator at your dairy operation located at Melrose, MN, confirmed that you offered animals for sale for slaughter as food in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and that you adulterated animal drugs within the meaning of Section 501(a)(5).

On or about March 27, 1997, you sold a dairy cow to [REDACTED]. This animal was slaughtered at [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of gentamicin at 4.70 parts per million (ppm) in the kidney. No tolerance has been established for gentamicin in the edible tissues of cattle. This causes the food to be adulterated within the meaning of Section 402(a)(2)(D) of the Act.

Our investigation found that you are adulterating the drug gentamicin when you use it on dairy cows within the meaning of Section 501(a)(5) of the Act in that you fail to use the drug in conformance with its labeling or the veterinarian's

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extra-label use directions. You are using the drug at higher than labeled dosages, you are not following the prescribed route of administration, and you are not adhering to the prescribed withdrawal times. These practices cause the drug to be unsafe to use.

In addition, 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 you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

Also, on or about June 16, 1997, you sold an adulterated dairy cow to [REDACTED] [REDACTED] USDA analysis of tissue samples collected from this animal identified the presence of gentamicin at 2.30 ppm in the kidney, penicillin at 0.15 ppm in the kidney, and penicillin at 0.10 ppm in the liver. Again, no tolerance has been established for gentamicin in the edible tissues of cattle. A tolerance of 0.05 ppm has been established for penicillin in the edible tissues of cattle.

The above is not intended to be an all-inclusive list of violations. You are responsible for the correct use of drugs used in your dairy operation. In addition, as a producer of animals that may be offered for food, you are responsible for assuring that your overall operation and the foods you may 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.

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 firm into compliance with the law. Your response should include an explanation of each step taken to correct the

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violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date the corrections will be completed. Your reply should be directed to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,



James A. Rahto
Director
Minneapolis District

CAH/ccl

xc: D.V.M.