



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

94553d

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 1000135249

February 11, 2004

Ronald Hilarides, Managing Partner  
Peter Schaafsma, Partner  
S & H Dairy  
4125 Bentley Road  
Oakdale, California 95361-7935

**WARNING LETTER**

Dear Messrs. Hilarides and Schaafsma:

An investigation of your dairy operation in Oakdale, California conducted by Food and Drug Administration (FDA) investigators on December 9 and 12, 2003, confirmed that you offered an animal 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), 21 U.S.C. §§ 342(a)(2)(C)(ii) and 342(a)(4). You also caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351, because the drugs were used in a manner that does not conform with their approved use or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (21 C.F.R. § 530).

On or about October 9, 2003, you consigned a cow identified by United States Department of Agriculture (USDA) laboratory report number 434889 to be slaughtered for human food to [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of neomycin at 18.85 parts per million (ppm) in the kidney. A tolerance of 7.2 ppm has been established for residues of neomycin in cattle kidney at 21 C.F.R. § 556.430. The presence of neomycin above established tolerance levels in the edible tissues from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

A food is adulterated under 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 applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions whereby

medicated animals bearing possibly harmful drug residues could enter the food supply. For example, our investigator observed the following:

1. Your firm fails to maintain a complete, written medication treatment record system for your animals that includes all treatments, the date of treatment, the amount of each drug administered, the route of administration, and the person who administered each drug;
2. Your firm fails to follow labeled directions for the following drugs:

a. [REDACTED]  
The labeled directions specify that milk from treated cows must not be used for food during the first 72 hours after calving. However, FDA learned that you routinely allow newborn bull calves, destined for slaughter, to suckle from dams that have been treated with the [REDACTED] before the 72-hour withdrawal period specified on the label.

b. [REDACTED]  
The labeled directions state that no more than 10 mL [REDACTED] should be injected at any one site in adult livestock. However, you administer 30 mL [REDACTED] mixed with sterile water and infuse this into the uterus of dairy cows with retained placenta.

3. Your firm fails to maintain a drug inventory/accountability system.

You adulterated animal drugs within the meaning of Section 501(a)(5) of the Act when you failed to use the drugs in conformance with their approved conditions of use or the extralabel use regulations at 21 C.F.R. § 530. Extralabel use of animal drugs is permitted only on the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in compliance with the criteria set forth at 21 C.F.R. § 530. Because your use of the drug [REDACTED] on your cattle did not conform with the drug's approved labeling or the extralabel use regulations, the drugs are unsafe under Section 512(a) of the Act. As a result, your use of these drugs caused them to be adulterated within the meaning of Section 501(a)(5) of the Act.

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 assuring that your overall operations and the food you distribute are in compliance with the law.

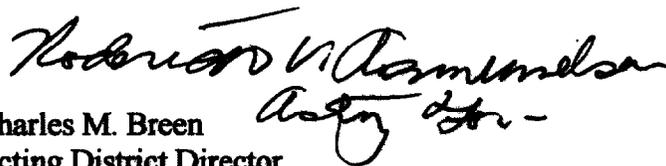
It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should 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 a seizure and/or injunction, without further notice.

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 into compliance with the law. Your response should include each step being taken, that has been taken, or that 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 response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Charles M. Breen  
Acting District Director  
San Francisco District