



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

May 28, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 36-03

Michael E. Musser
Partner
Shady Grove Dairy
13485 Bon View Ave.
Ontario, CA 91761

Dear Mr. Musser:

Our records reflect that you are a partner of Shady Grove Dairy, located at 13485 Bon View Ave., Ontario, CA. An investigation of your dairy operation conducted by our investigator on March 11-13, 2003, confirmed that you offered a cow 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). The inspection also revealed you caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act.

A food is adulterated under 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 further adulterated under Section 402(a)(4) of the Act if it has been held under conditions whereby it may have been rendered injurious to health.

On or about January 9, 2003, you sold a culled dairy cow identified by USDA Laboratory report 265786 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the liver at 0.25 parts per million (ppm) and in the kidney at 0.63 ppm. A tolerance of 0.5 ppm has been established for residues of penicillin in the edible tissues of cattle (Title 21, *Code of Federal Regulations*

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(CFR), Section 556.510). The presence of this drug at the level reported in edible tissue from this animal causes the food to be adulterated with the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation found that you hold animals under conditions whereby 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 in edible tissues. Food from animals held under such conditions is adulterated under the Act.

It was further determined that you are using drugs in a manner contrary to their approved labeling. Specifically, injectable penicillin, such as ██████████, that you use on dairy cattle, is labeled for use at 1 cc per hundred pounds of body weight. Your use of 50 cc injections is greater than the approved labeling. Such extra-label use is not permitted, except by or under the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship (21 CFR § 530.10). Such use must also comply with the limitations set forth for specific extra-label uses (21 CFR § 530.11). Your use of drugs in any manner other than as labeled causes the drug to be adulterated under Section 501(a)(5) of the Act. Further, your use of this drug in dairy cows without following the labeled withdrawal period causes the drug to be unsafe and, therefore, adulterated.

You should not consider this letter to be an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods that you distribute are in compliance with the law.

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

~~You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action being initiated by FDA without further informal notice. These actions may include, but are not limited to, seizure and/or injunction.~~

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to bring your firm into compliance with the law. Your response should include each step you have taken or will take to correct the violations and to prevent the recurrence of similar violations. If corrective action cannot be taken

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within fifteen working days, state the reason for the delay and the time within which such corrections will be made. If you have any questions or need clarifications regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer, at telephone number (949) 798-7739.

Your written response should be directed to:

Scott A. Goff
Acting Director, Compliance Branch
U.S. Food and Drug Administration
19900 MacArthur Blvd., Ste. 300
Irvine, CA 92612-2445

Sincerely,

Handwritten signature of Scott A. Goff, A.D.D. for

Alonza E. Cruse
District Director