



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M35707

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

Via Federal Express

Our Reference: 29-39624

March 21, 2000

John A. Slenders, Partner
Antone A. Slenders, Partner
Slenders Dairy
P.O. Box 936
Chowchilla, California 93610

WARNING LETTER

Dear Messrs. Slenders:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on February 18 through 24, 2000, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

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. On January 11, 2000, you consigned a dairy cow (identified by USDA laboratory report number 403892) to be slaughtered for human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this cow revealed the presence of penicillin in the liver at 0.12 parts per million (ppm), and in the kidney at 0.07 ppm. Presently, the tolerance level for penicillin in the uncooked edible tissues of cattle is 0.05 ppm.

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 which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.
2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
3. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling.
4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Microcillin brand of penicillin G procaine within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Your veterinarian's prescription for penicillin specifies the drug is for the treatment of metritis in dairy cows. In addition, the prescription indicates a dosage of 4 cubic centimeters (cc) per 100 pounds of body weight twice daily and a withdrawal time of eighteen days prior to slaughter. Your practice of administering 40cc per day for the treatment of foot rot and/or displaced abomasum in your dairy cows is not in conformance with your veterinarian's prescription. Administering penicillin, coupled with an inadequate withdrawal time, is likely the cause of the illegal residue found in the aforementioned cow.

Failure to comply with the label instructions on drugs you use to treat your cows and calves presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that 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 offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Slenders Dairy has established a history of offering animals for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of January 11, 1989, through January 11, 2000, Slenders Dairy sold nineteen cows and calves for human food which were found to contain illegal drug residues. During this same period Slenders Dairy sold ten calves which were found to be CAST positive due to the possible presence of harmful levels of antibiotics. As a result of the violative residues, the FDA conducted inspections of Slenders Dairy on June 29 and 30, 1989, November 27, 1990, May 13 and 14, 1992, November 15 and 17, 1995, and on February 18 through 24, 2000. In addition, the State of California conducted two inspections of Slenders Dairy on November 21 through 28, 1994, and on October 18, 1999. During these inspections Slenders Dairy was warned that it is illegal to market animals with illegal levels of antibiotics. Also, USDA sent Slenders Dairy a letter for each instance in which their analysis found violative levels of drug residues. Slenders Dairy has failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, please notify our Fresno office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, Investigator, United States Food and Drug Administration, 2202 Monterey Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,

Charles D. Moss

Acting Director
San Francisco District

cc:

