



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

msn

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

December 7, 1998

Janet M. Slegers
Owner
Aspen Dairy
10241 Edison Avenue
Chino, CA 91710

WL-15-9

Dear Ms. Slegers:

An investigation at your dairy operation located at 10241 Edison Avenue, Chino, California, conducted by our investigator on November 23 and 24, 1998, confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(4) and 402(a)(2)(ii)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about October 14, 1998, you sold a culled dairy cow identified by USDA report #356418 for slaughter as human food at [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney at 1.30 parts per million (ppm). A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle. The presence of this drug in edible tissues from this animal causes the food to be adulterated.

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 assuring that medicated animals 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.

You are adulterating the drug, [REDACTED], brand of penicillin G procaine that your firm uses on cows within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug at a higher than labeled dosage, such as administering a 30-35 ml dose of penicillin per injection site, is not only contrary to the label recommended

maximum of 10 ml per injection site, but it results in a total dose greatly in excess of that approved in the product labeling and causes the drug to be unsafe for use.

While a licensed veterinarian, under certain well-defined circumstances, may administer or prescribe drugs in a manner not approved in the labeling, such authority has not been extended to non-veterinarians under any circumstances.

The above is not intended to be an all-inclusive list of violations. As a producer of animals which are 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.

You should take prompt action to correct the above violations and to assure that the procedures you have established will prevent their recurrence. Failure to do so may result in regulatory action without further notice, such as injunction.

You should be aware that it is not necessary for you to have personally shipped an animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please advise this office in writing within fifteen (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 to correct the violations and prevent their recurrence. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which such corrections will be made.

Your response should be directed to:

Barbara J. Rincon
Investigator
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612-2445

Sincerely,


Elaine C. Messa
District Director
Los Angeles District

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cc: Steve Wong, Branch Chief
State of California
Department of Food & Agriculture
P.O. Box 942871
Sacramento, CA 94271-0001