



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m38794

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

WARNING LETTER

JUN 21 2000

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Mr. Fredrick A. Abacherli
Abacherli Dairy
29875 Newport Rd.
Menifee, CA 92584

W/L 64-00

Dear Mr. Abacherli:

A tissue residue report from the United States Department of Agriculture (USDA) and an inspection of your dairy operation conducted March 16 through 17 of this year by our investigator has 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), and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about January 11, 2000, you sold a culled dairy cow identified with State-Federal backtag number 93 GH 8336 (premise ID 33-03025/314) and USDA laboratory report number 307967 for slaughter as human food. The USDA analysis revealed penicillin levels at 0.24 parts per million (ppm) in kidney. Because you do not record the backtag number nor link it with the eartag number recorded when animals are culled, you were unable to identify this animal for our investigator. However, an animal you culled on January 11, 2000 and identified with eartag number 5441 was treated with an estimated 100 c.c. of penicillin on or about December 31, 1999. A tolerance of 0.05 ppm has been established for the uncooked edible tissues of cattle in Title 21, Code of Federal Regulations (CFR), Section 556.510. The presence of this drug in the edible tissue of this animal causes the food to be adulterated under section 402 (a)(2)(C)(ii) of the Act.

Our inspection also determined that you hold animals under such inadequate conditions that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate record keeping system that records all pertinent information to assure that drugs are used as labeled or as prescribed by a veterinarian. Because of these inadequacies, you cannot ensure that animals at your dairy have been withheld from slaughter for the appropriate period of time to permit depletion/elimination 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.

In addition, you are adulterating the gentamicin and spectinomycin that your dairy uses on calves within the meaning of section 501(a)(5) when you fail to use the drug in conformance with its approved labeling or as prescribed by a veterinarian. Your use of the drug at higher than labeled dosages, for

animals/conditions/indications not stated on the label and/or without following the labeled withdrawal period causes the drug to be unsafe for use.

The above-identified violations are not intended to be an all-inclusive list of deficiencies at your dairy. As a producer of animals that are offered for use as human food, you are responsible for assuring that your establishment is in compliance with all requirements of the federal regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action could include, but is not limited to, seizure and/or injunction.

In addition to the specific violations noted above, we have the following comments:

Government records available to us indicate there has been at least three additional instances of your offering drug adulterated animals for sale as human food since 1996 with two of the three residues occurring in the past year. Specifically, your dairy delivered a cow, back tag number 93-GM-1978, USDA laboratory report 265563 dated September 22, 1999, with penicillin levels of 0.10 ppm in kidney, back tag number 93-GH-9973, USDA laboratory report 356504 dated August 12, 1999, with penicillin levels of 0.32 ppm in kidney and back tag number 93-GL-9817, USDA laboratory report 383936 dated August 6, 1996, with penicillin levels of 0.06 ppm in kidney and sulfadimethoxine levels of 0.69 ppm in liver and 0.48 ppm in muscle. The tolerance levels for sulfadimethoxine in all edible tissues of cattle are set by 21 CFR, Section 556.640 at 0.10 ppm.

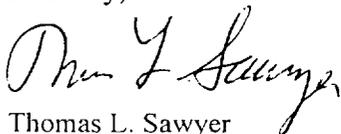
You have received two previous Notices of Warning from the State of California Department of Food and Agriculture for violations very similar to those outlined during the current inspection. We consider the continued offering of animals containing illegal drug tissue residues for sale in interstate commerce a serious violation and are very concerned that you have not voluntarily corrected this problem by implementing a record keeping system designed to prevent the recurrence of the violation.

Our investigator observed several expired drug products in the active drug storage area. The storage of these expired drug products in the same area as the non-expired drugs can lead to the accidental use of these products.

Please notify this office in writing within 15 working days of receipt of this letter of the specific actions taken to correct the noted violations and prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Please direct your written response to the attention of:

Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,



Thomas L. Sawyer
Acting District Director