



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M3353n

OCT 6 1999

WARNING LETTER

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

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Kenneth E. Koolhaas, Manager
Koolhaas Dairy
14717 Haven Avenue
Chino, CA 91710

WL-01/00

Dear Mr. Koolhaas:

A tissue residue report from the United States Department of Agriculture (USDA) and an investigation of your dairy operation conducted July 22nd and 23rd 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 April 9th, 1999, you sold a culled dairy cow identified with State – Fed back tag number 93-GM-4911, Dairy Beef Quality Assurance back tag number 36-01535-396 and USDA laboratory report number 265479 for slaughter as human food at [REDACTED]. The USDA analysis revealed sulfadimethoxine levels at 6.8 parts per million (ppm) in liver, 1.2 ppm in muscle tissue. A tolerance of 0.1 ppm has been established for the uncooked edible tissues of cattle in Title 21, Code of Federal Regulations (CFR), Section 556.640. 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 investigation 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, including medication dosages, to assure that drugs are used as labeled or as prescribed by your veterinarian. Because of these inadequacies, you cannot ensure that animals medicated by you have been withheld for 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 drug "[REDACTED]" brand of sulfadimethoxine that your firm uses on cattle 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 higher than labeled dosages 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 have been several additional instances of your offering drug adulterated animals for sale as human food over the past several years. For example, your dairy delivered the following animals for food use: back tag number 93-GM-9447, USDA laboratory report 307395 dated December 2, 1997, with penicillin levels of 0.28 ppm in kidney; back tag number 93-GM-4253, USDA laboratory report 383647 dated April 18th, 1996, with penicillin levels of 0.2 ppm in liver; and back tag number 93-GM-3469, USDA laboratory report 251351 dated July 28th, 1995, with penicillin levels of 0.1 ppm in kidney. The tolerance levels for Penicillin in all edible tissues of cattle are set by 21 CFR, Section 556.510 at 0.05 ppm.

For your information, when your veterinarian provides instructions for the use of a drug, such as penicillin, which results in a total dose far in excess of that approved in the product labeling, the withdrawal time which is specified in the labeling may not be sufficient to assure the animal will not have drug residues above the legal tolerances when offered for sale as human food.

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:

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

Sincerely,


Acting District Director