



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35
Public Health Service
Food and Drug Administration
M33051

FEB 1 2000

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Fred Schakel, Owner
Fred Schakel Dairy # 2
5815 Sumner Avenue
Chino, CA 91710

W/L 23-00

Dear Mr. Schakel:

A tissue residue report from the United States Department of Agriculture (USDA), and an investigation of your dairy operation conducted October 29th through November 2nd, 1999 by our investigator has confirmed that you offered animals 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). In addition, you may have caused animal drugs to become adulterated within the meaning of Section 501 (a)(5) of the Act.

On or about August 11th, 1999, you culled three dairy cows identified with premise back tag numbers 381, 382 and 383 for slaughter as human food at [REDACTED]. Cow # 383 was sampled and tested by USDA (USDA laboratory report number 356400). The USDA analysis revealed gentamicin levels at 6.40 parts per million (ppm) and neomycin levels of 166.0 ppm in kidney. A tolerance for neomycin of 7.2 ppm has been established for the uncooked edible kidney of cattle in Title 21, Code of Federal Regulations (CFR), §556.430. A tolerance level for gentamicin has not been established for the edible tissues of cattle. The presence of these drugs in the edible kidney of this animal causes the food to be adulterated under section 402 (a)(2)(C)(ii) of the Act.

In addition, 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 two years. For example, your dairy delivered the following animals for food use: back tag number [REDACTED]-2977, USDA laboratory report 265447, with streptomycin levels of 2.60 ppm in kidney; back tag number [REDACTED]-3635, USDA laboratory report 265470, with gentamicin levels of 1.30 ppm in kidney; and back tag number [REDACTED]-0498, USDA laboratory report 404027, with gentamicin levels of 0.63 ppm in kidney. There is no tolerance level established for streptomycin or gentamicin in the kidney of cattle.

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. As used here, inadequate conditions refers to the record keeping, drug usage and culling practices at your dairy. 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. Additionally, you do not obtain medication/treatment information for purchased replacement heifers. Because of these inadequacies, you

cannot ensure that animals 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 drugs Today brand cephalixin, Lincomix brand lincomycin and Terramycin brand tetracycline within the meaning of section 501 (a)(5) when you fail to use these drugs in conformance with their approved labeling and without written directions from your veterinarian. Your use of these drugs at higher than labeled dosages and/or without following the labeled withdrawal period causes the drugs to be adulterated.

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:

When your veterinarian provides instructions for the use of a drug, 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 L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,


Thomas A. Allison
Acting District Director