



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m3024n

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

APR 6 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Herman Haringa
Haringa Dairy
8552 Kimball Avenue
Chino, CA 91710

W/L 48-00

Dear Mr. Haringa:

A tissue residue report from the United States Department of Agriculture (USDA) and an investigation of your dairy operation conducted March 1st 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 14th, 2000, you sold a culled dairy cow identified with State – Fed back tag number [REDACTED] and USDA laboratory report number 265598 for slaughter as human food at [REDACTED]. The USDA analysis revealed penicillin levels at 0.22 parts per million (ppm) in liver. 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 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 to assure us that drugs used by you, your contract calf grower or your contract breeder 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 for slaughter for the appropriate period of time to permit depletion/elimination

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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 tetracycline powder 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, for 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 one additional instance of your offering drug adulterated animals for sale as human food since 1997. Your dairy delivered a cow, back tag number [REDACTED] USDA laboratory report 274499 dated October 13th, 1997, with sulfadimethoxine levels of 0.55 ppm in liver and 0.36 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.

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,



Acting District Director