



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94427d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94602-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 3004097325

November 17, 2003

Hein Hettinga
E. J. (Amos) Degroot
Partners
Pahrump Dairy
556 North Blagg Road
Pahrump, NV 89041

WARNING LETTER

Dear Messrs. Hettinga and Degroot:

Tissue residue reports from the United States Department of Agriculture (USDA) and an inspection of your dairy farm located at 556 North Blagg Road, Pahrump, NV 89041, on July 28-30, 2003, by a Food and Drug Administration (FDA) investigator, 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), and that you caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act.

On July 31, 2002, you sold a cull dairy cow, identified as animal [REDACTED] (back tag [REDACTED] USDA retain tag #43404899), for slaughter as human food. USDA analysis of tissue samples collected from that animal (Lab Report Serial #427795) identified the presence of penicillin in the kidney at 0.11 ppm (parts per million).

On November 29, 2002, you sold a cull dairy cow, identified as animal [REDACTED] (back tag [REDACTED] USDA retain tag #43408772), for slaughter as human food. USDA analysis of tissue samples collected from that animal (Lab Report Serial #434099) identified the presence of sulfadimethoxine in the liver at 31.72 ppm and in the muscle at 32.21 ppm.

On December 4, 2002, you sold a cull dairy cow, identified as animal [REDACTED] (back tag [REDACTED] USDA retain tag #43409913), for slaughter as human food. USDA analysis of tissue samples collected from that animal (Lab Report Serial #434110) identified the presence of penicillin in the kidney at 0.13 ppm.

On December 11, 2002, you sold a cull dairy cow, identified as animal [REDACTED] or [REDACTED] (back tag [REDACTED] USDA retain tag #43409295), for slaughter as human food. USDA analysis of tissue samples collected from that animal (Lab Report Serial #434115) identified the presence of sulfadimethoxine in the liver at 0.21 ppm and in the muscle at 0.21 ppm.

On January 22, 2003, you sold a cull dairy cow, identified as animal [REDACTED] (back tag [REDACTED] USDA retain tag #43410368), for slaughter as human food. USDA analysis of tissue samples collected from that animal (Lab Report Serial #434136) identified the presence of sulfadimethoxine in the liver at 2.91 ppm and in the muscle at 3.94 ppm.

Presently, the tolerance level for penicillin in the uncooked edible tissues of cattle is 0.05 ppm (Title 21 Code of Federal Regulations § 556.510(a)), and the tolerance level for sulfadimethoxine in the uncooked edible tissues of cattle is 0.1 ppm (Title 21 Code of Federal Regulations § 556.640(b)). The presence of either drug at a level above the tolerance in edible tissues of these animals causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act.

A food is adulterated under Section 402(a)(4) of the Act if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for slaughter as food, 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 animals have been treated only with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you 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 under Section 402(a)(4) of the Act.

The introduction or delivery for introduction into interstate commerce of any adulterated food is prohibited under Section 301(a) of the Act. It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The drug Pen-Aqueous (penicillin G procaine) injectable suspension U.S.P. is adulterated within the meaning of Section 501(a)(5) since you fail to use it in conformance with its approved labeling. The label states that no more than 10 mL (cc) should be injected at any one site in adult livestock, whereas you routinely administer the drug as a single intramuscular 60-cc injection in one site on the first day and as a single intramuscular 40-cc injection in one site on the second day. You also administer this drug intrauterine to

treat retained placentas, an extra label use. This drug or some other penicillin G procaine was administered to the animals listed above that were found to contain illegal penicillin residues.

The drug Albon (sulfadimethoxine) bolus is adulterated within the meaning of Section 501(a)(5) since you fail to use it in conformance with its approved labeling. The label states that animals weighing 1,000-1,200 lbs. should be administered 2 boluses the first day followed by 1 bolus daily for the following three or four days, whereas you routinely administer the drug in 2 boluses the first and second day of treatment followed by 1 bolus on the third day. This drug was reportedly administered to the animals listed above that were found to contain illegal sulfadimethoxine residues.

Our investigator reported other drugs used by your dairy in a manner contrary to label directions, including some administered to the animals listed above. Animal [REDACTED] was treated with Oxy-Mycin 100 (oxytetracycline HCl) injection on July 16, 17, 18, 19, and 24, 2002, and then sold for slaughter seven days later, even though the label warns to discontinue treatment at least 22 days prior to slaughter. Animal [REDACTED] was treated with Quartermaster (penicillin-dihydrostreptomycin) in oil on January 15, 2003, and then sold for slaughter seven days later, even though the label warns that animals infused must not be slaughtered for food within 60 days from time of infusion.

The manner in which you use these and other drugs outside of their FDA-approved labeling causes them to be unsafe within the meaning of Section 512 of the Act.

At the conclusion of the inspection, Form FDA 483, Inspectional Observations, was issued to Michael J. Kwiatkowski, Co-Manager, and discussed with Maximo Rubio, Herdsman/Manager, [REDACTED] Assistant Herdsman; and Robert D. Petty, DVM. A copy of this form is attached for your ready reference.

The violations listed above are not meant to be all-inclusive. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct the violations. If you cannot complete all corrections before responding, we expect you will explain the reason for any delay and the time period within which the corrections will be completed.

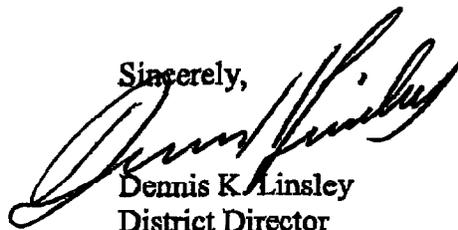
Your response should be directed to Paul A. Peterson, Compliance Officer, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502. If you have any

Hein Hettinga & E. J. (Amos) Degroot
Pahrump Dairy

4

questions regarding any issue in this letter, you may contact Mr. Peterson at (510) 337-6856.

Sincerely,



Dennis K. Linsley
District Director

Attachment: Form FDA 483, Inspectional Observations

cc: Hein Hettinga
President
Hettinga Dairies
17190 Cucamonga Ave.
Corona, CA 92880

E. J. (Amos) Degroot
President
Rockview Dairies, Inc.
7011 Stewart & Gray Rd.
P.O. Box 668
Downey, CA 90241