

as sent to ~~SEA~~ HFI-35

5/28/97
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DEPARTMENT OF HEALTH & HUMAN SERVICES

M 885N

Public Health Service

Food and Drug Administration
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Pacific Region
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May 7, 1997

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HAND DELIVERED

In reply refer to Warning Letter SEA 97-19

WARNING LETTER

Peter J. Veeman, Owner
Veeman Dairy
6629 Champoeg Road
Saint Paul, Oregon 97137

Dear Mr. Veeman:

An investigation at your dairy operation located at Saint Paul, Oregon, conducted on April 22, 1997, confirmed that you offered an animal for sale for food in violation of Sections 402(a)(2)(D) 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).

On March 18, 1997, you sold a cow identified with ear tag number 7462 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of 0.1 ppm of penicillin in the liver and 0.09 ppm of penicillin in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in edible tissues of cattle. The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(D).

Our investigation also found that you hold animals under conditions which allow medicated animals bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for: a) assuring that drugs are used in a manner not contrary to the directions contained in the labeling; b) and 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 within the meaning of section 402(a)(4) of the Act.

You are adulterating the drug [redacted] brand of penicillin that your firm uses on cows within the

Peter J. Veeman, Owner
Veeman Dairy, St. Paul, OR
Warning Letter SEA 97-19
Page 2

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 doses and injecting more drug than the label allows in one location causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for 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, such as seizure and/or injunction.

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.

On May 12, 1994, following an inspection at your dairy, the FDA sent you Warning Letter SEA 94-41 for your dairy's failure to withhold a medicated cow from slaughter for appropriate period of time to allow depletion of potentially hazardous drug residues. USDA analysis of tissue from the cow identified the presence of penicillin in the kidney and liver at 0.14 ppm and 0.07 ppm respectively. A tolerance of 0.05 ppm has been established for residues of penicillin in cows. At the close of the inspection the investigator discussed and left with you a list of inspectional observations that included: a) failure to follow label directions for penicillin administered, in that the dosage was in excess of the label directions; b) failure to maintain adequate and complete medication treatment records; c) failure to have a system to review treatment records prior to offering the animal for slaughter; d) and storing drugs at inadequate temperatures.

On June 2, 1994, you informed the FDA that you would begin using a drug treatment and residue test record that identified the cow, date of treatment, diagnosis/treatment, dosage, route of administration, individual administering drug, withdrawal time, and residue tests.

Again on November 10, 1994, following an inspection at your dairy, the FDA sent you Warning Letter SEA 95-08 for your dairy's

Peter J. Veeman, Owner
Veeman Dairy, St. Paul, OR
Warning Letter SEA 97-19
Page 3

failure to withhold five medicated veal calves from slaughter for appropriate period of time to allow depletion of potentially hazardous drug residues. USDA analysis of tissue from these calves identified the presence of neomycin in the kidney and liver of all five calves ranging in levels from 39.40 ppm to 1.12 ppm. USDA also identified the presence of penicillin in the kidney and liver, at 1.83 ppm and 0.77 ppm respectively, of one of the calves. A tolerance of 0.25 ppm has been established for residues of neomycin and 0.05 ppm for residues of penicillin in calves. At the close of the inspection the investigator discussed and left with you a list of inspectional observations that included: a) failure to follow label directions in that labeled pre-slaughter withdrawal time was not followed; b) feeding calves milk from treated cows which were then sent to slaughter; c) and holding expired drugs in the daily use drug storage area.

On December 1, 1994, you informed the FDA that you have discontinued treating bull calves with [REDACTED] and they are now fed a non medicated milk replacer. You also stated that you do not intend to sell any bull calves through the auction yard unless they are weaned.

We will discuss these issues on May 8, 1997, when we will meet at the FDA Resident Post in Portland, Oregon. As we discussed on the phone on May 6, 1997, the FDA is concerned with the continued recurrence of these same type of violations from your dairy. I expect that during the meeting you will be able to commit to corrective actions that will bring your operation into compliance and the timeframe within which the corrections will be completed. If you cannot provide a corrective action plan during the meeting then I will expect you to advise this office in writing within fifteen (15) working days of the meeting of the steps you will take to ensure violations of this nature to not recur. Your response should be directed to Richard S. Andros, Compliance Officer, at the above address.

We want to work with you to put into place measures that will be both effective and lasting. The presence of violative levels of drugs in the food from slaughtered animals is a human health concern.

Regulation of the Nation's meat supply are responsibilities shared by the Food Safety Inspection Service (FSIS) and the Food and Drug Administration (FDA). The FDA regulates and inspects food other than red meat and poultry, regulates animal drugs, and determines if animal drugs can be legally introduced into the

Peter J. Veeman, Owner
Veeman Dairy, St. Paul, OR
Warning Letter SEA 97-19
Page 4

market. This includes establishing tolerances for residues of animal drugs in edible tissues. The FSIS is charged with ensuring that meat sold in interstate commerce within the U.S. is safe, wholesome, and free of adulterating residues. FSIS reports violative residues of drugs in meat to FDA for follow-up. Working together the two agencies can address consumer exposure to drug residues in the edible tissues of food animals.

By establishing good animal husbandry practices and animal medication practices at your dairy, which include detailed monitoring of medication given to your animals that may be used for human food and ensuring that these practices are both effective and lasting, we will be successful in stopping continued tissue residue violations from your dairy.

Sincerely yours,

Celeste M. Corcoran

Roger L. Lowell^{for}
District Director