



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M3217n

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

WARNING LETTER

June 29, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jim Bootsma, Jr, Owner
Jim Bootsma, Jr. (Dairy)
18500 Bridge St.
Lakeview, CA 92582

W/L 35-9

Dear Mr. Bootsma:

An investigation at your dairy operation located at 18500 Bridge Street, Lakeview, California, conducted by our investigator on May 25, 28 & June 1, 1999, confirmed that you offered animals for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

On or about 3/10/99, you sold a culled dairy cow identified by USDA Laboratory Report #356287 for slaughter as human food at [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of sulfamethazine in the muscle at 7.70 ppm and in the liver at 8.30 ppm. A tolerance of 0.10 ppm has been established for residues of sulfamethazine in the edible tissues of cattle. The presence of sulfamethazine above the established tolerance in edible tissue from this animal causes the food to be adulterated.

On or about 11/9/98, you sold a culled dairy cow identified by USDA Laboratory Report #356436 for slaughter as human food at [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney at 2.20 ppm and in the liver at 0.82 ppm. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle. The presence of penicillin above the established tolerance in edible tissue from this animal causes the food to be adulterated.

On or about 11/6/98, you sold a culled dairy cow identified by USDA Laboratory Report #356434 for slaughter as human food at [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of sulfadimethoxine in the muscle at 0.97 ppm and in the

Letter to Mr. Bootsma, Jr.
June 29, 1999
Page 2

liver at 1.40 ppm. A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle. The presence of sulfadimethoxine above the established tolerance in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals 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 the conditions of 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 the appropriate period of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

The following new animal drugs found on your premises, are adulterated under Section 501(a)(5) of the Act, when they are used, as was indicated to our investigator, in a manner contrary to their approved labeling:

1. Injectable penicillin G procaine is labeled for a dosage of 1cc/100 lbs with a maximum of 10 ccs per injection site. Your use of 100 ccs per cow as well as the administration at only 2 injection sites is greater than labeled and causes the drug to be unsafe to use.
2. Your use of injectable penicillin combined with injectable dexamethasone for injection into a quarter is not in accordance with the labeled directions for either drug. Your administration in this manner causes the drugs to be unsafe to use.
3. Your intrauterine infusion of 1 gallon of water with 8 oz of propylene glycol with powdered tetracycline and injectable oxytetracycline is not in accordance with the labeled directions for any of these products. Your administration in this manner causes the drugs to be unsafe for use.
4. Oral sulfadimethoxine boluses are labeled for use 2 boluses on the first day and one bolus on the subsequent 2-3 days. Your use of two boluses for 2-3 days is greater than labeled and causes the drug to be unsafe to use.

While a licensed veterinarian, under certain well-defined circumstances, may administer or prescribe drugs in a manner not approved in the labeling, such authority has not been extended to non-veterinarians under any circumstances.

Letter to Mr. Bootsma, Jr.
June 29, 1999
Page 3

The above is not intended to be an all-inclusive list of violations. The specific violations noted in this letter and in the FDA Form 483 issued at the closeout of the inspection maybe symptomatic of underlying problems in your firm's operations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operations and the food you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to assure that the procedures you have established will prevent their recurrence. Failure to do so may result in regulatory action without further notice, such as injunction.

Please note that it is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please advise this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step that has been taken to correct the violations and prevent their recurrence. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which such corrections will be made.

If you have any questions or concerns regarding this letter please contact Barbara J. Rincon, Consumer Safety Officer, at (949) 798-7739.

Your response should be directed to:

Thomas L. Sawyer
Director Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd., Ste. 300
Irvine, CA 92612

Sincerely,


Thomas A. Allison
Acting District Director