



DEPARTMENT OF HEALTH & HUMAN SERVICES

d19066
Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

July 9, 1998

Ref: 98-DAL-WL-#45

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. N. Mark Reif, D.V.M.
Clayton Veterinary Consultants, Ltd.
1311 S. First
Clayton, New Mexico 88415

Dear Dr. Reif:

An investigation of your client, Sunrise Farms, Inc., Boise City, Oklahoma, and of your veterinary practice on February 23, 1998, confirmed that you prescribed Penicillin G Procaine injectable, for the treatment of a uterine infection, to dairy animal #8012 owned by Sunrise Farms causing the adulteration of food (the edible tissues of a slaughtered cow) in violation of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act). A food is adulterated if it bears or contains a new animal drug (or conversion product thereof) which is unsafe within the meaning of Section 512 of the Act [Section 402(a)(2)(C)(ii)]. Additionally, as the prescribing veterinarian assuming the responsibility for the administration of the injectable penicillin and its conditions of use, you failed to ensure that your directed withdrawal period was observed, rendering the drug adulterated under Section 501(a)(5) and unsafe within the meaning of Section 512 of the Act.

The investigation revealed that on November 8 through 11, 1997, dairy animal #8012 was administered injectable penicillin antibiotic by Sunrise Farms for the treatment of a uterine infection. You had previously provided the dairy farm with a standing order for medicating animals on the dairy farm in the form of a Treatment Schedule. The drug was administered at the rate of 25cc per day (3cc/cwt) per your standing orders for the 4 days. The animal was sold to a slaughter buyer/dealer on November 12, 1997, and was subsequently offered for sale for slaughter as food on November 13, 1997.

Animal #8012 was delivered for slaughter as food at Booker Packing Company, Inc., Highway 15 East, Booker, TX. The animal was found by USDA (Lab Report #377550) to bear an illegal residue of penicillin at 0.09ppm in kidney tissue. A tolerance of 0.05ppm has been established for residues of penicillin in the edible tissues of cattle (Title 21, Code of Federal Regulations, 556.510). The presence of this drug in edible tissue from this animal causes the food to be adulterated [Section 402(a)(2)(C)(ii)].

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Our investigator determined that you prescribed the penicillin on an extralabel use basis and that the dosage rate administered was 3-times the manufacturer's labeled dosage rate for administration of the product. The drug is labeled and intended for the treatment of shipping fever in cattle. The Treatment Schedule for Sunrise Farms includes directions for 14 day withdrawal of the animal treated in this manner and advises pre-slaughter residue testing should be performed.

You, as the attending veterinarian, did not ensure these instructions were followed prior to the animal being offered for sale for slaughter as food. The investigator determined that you, as the Staff Veterinarian for Sunrise Farms, along with the Farm Manager and Herdsman share responsibility in the decisions on when to medicate and when to offer an animal for sale for slaughter.

As the prescribing veterinarian of injectable penicillin to animal #8012 bearing violative drug residues at the time of slaughter for food, you share with the dairy, as well as the slaughter buyer/dealer in the responsibility for the violative tissue residue. Further, your failure to assure that the animal was withdrawn from the drug and that residue tests were performed, assuring no residue existed, caused the adulteration of the drug [Section 501(a)(5)].

You should be aware of the limitations and the conditions established for extralabel drug use or intended extralabel use in animals (Title 21, CFR, Part 530 - Extralabel Drug Use In Animals). A valid veterinarian-client-patient relationship must be established and a careful diagnosis and evaluation of the conditions for which an extralabel drug is to be used must be made by the veterinarian. The limitations established (21 CFR 530.11) do not permit extralabel use resulting in any residue above an established tolerance. The extralabel use criteria requires that substantially extended withdrawal periods be established for edible products of food animals. The withdrawal period is to be supported by appropriate scientific information, and the veterinarian is required to maintain records of the specified withdrawal. Additionally, the veterinarian is required to take appropriate measures to assure that assigned time frames for withdrawal are met and that no illegal drug residues occur. Your failure to meet these requirements results in the violation of Section 501(a)(5) of the Act (new animal drug adulteration) rendering the drug unsafe within the meaning of Section 512 of the Act.

You should take prompt action to correct the violations encountered at this time and assure that your future actions, in the administration of veterinary drugs to the food producing animals of your clientele, does not result in violative tissue residues of public health significance. Failure to take prompt action to correct the violations and to establish procedures whereby such violations do not recur may result in regulatory action without further notice such as seizure and/or injunction.

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You should notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to James R. Lahar, Compliance Officer, at the above letterhead address.

Sincerely yours,

A handwritten signature in black ink that reads "Robert D. Deminger". The signature is written in a cursive style with a large, prominent "D" and "M".

Joseph R. Baca
Dallas District Director

JRB:JRL:jab