



DEPARTMENT OF HEALTH & HUMAN SERVICES

94554d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

507

February 9, 2004

W/L: 29-04

Phil Bauer
President
Phillips Cattle Company
345 N. Maple Dr., Ste. 296
Beverly Hills, CA 90210

Dear Mr. Bauer:

Our records reflect you are the president of Phillips Cattle Company located at 910 Nichols Road, El Centro, CA. An investigation of your feedlot operation conducted by our investigator on December 8 and 9, 2003, confirmed that you offered animals for sale for slaughter as food which is in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (henceforth the "Act").

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. A food is further adulterated under Section 402(a)(4) of the Act if it has been held under conditions whereby it may have been rendered injurious to health.

On or about August 8, 2003, you sold a culled beef cow identified by USDA Laboratory report 256547 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of tilmicosin in the liver at 06.90 parts per million (ppm), in the muscle at 0.94 ppm and in the kidney at 9.13 ppm. A tolerance of 1.20 ppm in the liver and 0.10 ppm in the muscle has been established for residues of tilmicosin in cattle. There is no tolerance for tilmicosin in the kidney of cattle [21 CFR 556.735].

Our investigation also found that you hold animals under improper conditions whereby 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 medicated by you have been withheld from slaughter for the appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are considered adulterated under the Act.

It was further determined that you are using drugs in a manner contrary to their approved labeling. Such extra-label use is not permitted, except by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship, and otherwise in compliance with the limitations set forth for specific extra-label uses [21 CFR 530.10 and 530.11]. Your use of drugs in any manner other than as labeled causes those drugs to be adulterated under Section 501 (a)(5) of the Act because there is no approval for such use as required by Section 512 (a)(1)(B) of the Act.

- You are adulterating injectable tilmicon , such as [REDACTED] that you use on cattle in a manner contrary to the approved labeling. Injectable tilmicosin is labeled with a 28 day withdrawal time. Culling an animal for slaughter 2 days after treatment with tilmicosin does not conform to the approved labeling.
- You are adulterating injectable penicillin, such as [REDACTED] that you use on cattle in a manner contrary to the approved labeling. The labeled instructions are 1 cc per 100 pounds of body weight. Your use of 30 ccs per 800 pound animal does not conform to the approved labeling.

The above is not intended to be an all-inclusive list of violations. 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.

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 Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse which ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Additionally, it is not necessary for you to have an illegal drug residue in an animal to violate the law. We have reviewed your treatment protocols as presented to our investigator and have the following comments. All drugs are labeled with specific instructions on the dosage and route of administration as well as the disease or condition to be treated. Any deviation from the approved labeling is a violation of the law. For example, your protocol indicates you are using [REDACTED] without a withdrawal time. [REDACTED] is labeled with a 35 day withdrawal time. Your shipment of any animal treated with [REDACTED] prior to the 35 day withdrawal time is a violation of the law. Secondly, your protocol indicates that you are using a 28 day withdrawal for [REDACTED]. While this is the correct withdrawal time for intra-muscular injection, when [REDACTED] is administered subcutaneous there is a 38 day withdrawal time. Also we note that your protocols identify both [REDACTED]. These are two different forms of the drug and have different dosages and withdrawal times. Your treatment records and protocols should reflect this difference. Your protocol identifies a 2 day withdrawal time for [REDACTED]. This is incorrect. [REDACTED] when used as directed has a 4 day withdrawal time.

Review of the prescription forms presented to our investigator reveals that [REDACTED] has identified a 28 day withdrawal for [REDACTED] administered subcutaneously. The labeled withdrawal time as stated above is 38 days. As stated above, extra-label use of new animal drugs is authorized only when there is a valid veterinarian-client-patient relationship. A valid veterinarian-client-patient relationship can exist only where, among other requirements, a licensed and practicing veterinarian has recently seen and is personally acquainted with the keeping and care of the animals by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept. See 21 CFR 530.4(i). Our investigator noted that [REDACTED] address is located in Texas and that the prescription form appears to have originated from Texas. The distance between [REDACTED] Texas address and the California lot where the animals are kept raises questions about his ability and availability to visit, care for, and examine the animals in the manner required by the regulations. We recommend you evaluate your current veterinary practices.

Additionally, we strongly suggest you review your treatment protocols with your veterinarian, university extension services or state animal health officials to assure that you are using all medications in a legal and effective manner.

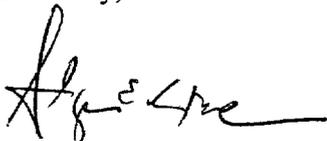
You should take prompt action to correct the above violations and to assure that the procedures you have established will prevent their recurrence. Failure to do so may result in regulatory action, such as injunction, without further notice. This letter constitutes official notification under the law and provides you an opportunity to correct the violations.

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 completed 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 need clarifications regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer at telephone number (949) 608-4439.

Your written response should be directed to:

Acting Director, Compliance Branch
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

Sincerely,



Alonza E. Cruse
District Director

Letter to Mr. Bauer
Page 4

Cc: Ross Jenkins
General Manager
Phillips Cattle Co.
505 E. Barioni
Imperial, CA 92551

Lonnie Foster
Yard Manager
Phillips Cattle Co.
910 Nichols Rd.
El Centro, CA 92243