



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Refer to: FEI 3003237389

Public Health Service ^{93676d}
Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5703

02-BLT-05

November 27, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joseph A. Houck, Owner
Joseph A. Houck Farm
22417 Belair Road
Culpeper, Virginia 22701

RE: Case No. 01-0057-VA

Dear Mr. Houck:

A Food and Drug Administration (FDA) inspection of your dairy located at 22417 Belair Road, Culpeper, Virginia on February 8, 2001, confirmed that you offered an animal for sale for slaughter as human food in violation of Section 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (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. In November 2000, you sold a culled dairy cow bearing back tag [REDACTED]. This cow was subsequently delivered to and sold for slaughter as human food at [REDACTED] on or about November 28, 2000. United States Department of Agriculture's (USDA) analysis of tissue samples collected from this animal identified the presence of [REDACTED] in the kidney. [REDACTED] is not approved for oral or injectable use in cattle. Therefore, there is no allowable tolerance for [REDACTED] in edible tissue of cattle. The presence of this drug in edible tissues of this animal causes the food from the animal to be adulterated. You should have received a letter dated January 1, 2001, from USDA concerning this matter.

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 sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply.

Our investigators noted the following conditions on your farm:

1. You lack adequate documentation for the treatment of the cattle, including the drug name and dosage administered to each animal, and the drug withdrawal time(s);
2. You lack a system for assuring that drugs are used in a manner that conforms to the approved labeling;
3. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal species, and;
4. You lack a system for assuring medicated animals have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.

Our inspection also revealed that the [REDACTED] residue came from your use of this drug on your dairy herd. You informed our investigators that the veterinarian had prescribed the [REDACTED] for the treatment of an injured cow in June 2000. However, you failed to consult with your veterinarian regarding the treatment in November 2000 of the injured dairy cow with back tag [REDACTED]. Although you had a prescription for [REDACTED], it was not for the treatment of this dairy cow. Use of this drug contrary to the approved conditions of use may only be done when a veterinarian is involved in the decision based on a valid veterinarian/client/patient relationship, no residue occurs, and other conditions described in Title 21, Code of Federal Regulations (21 CFR), Part 530 have been met. Our inspection also disclosed that the withdrawal time stated on the prescription label for [REDACTED] was [REDACTED] days for milk and [REDACTED] days for meat. Therefore, you adulterated [REDACTED] within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its approved labeling.

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.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

As a producer of animals offered for use as food, it is your responsibility to assure your operations are in compliance with the requirements of the Federal Food, Drug and Cosmetic Act. You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

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You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to the Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland, 21215, to the attention of Rosalie Bucey, Compliance Officer. Ms. Bucey may be reached at (410) 779-5417.

Sincerely,



Lee Bowers
Director, Baltimore District

cc:



cc: Dr. Perfecto Sanitiago, District Manager
USDA/FSIS
5601 Sunnyside Avenue
Suite 1-2288 B
Beltsville, Maryland 20705-5200

cc: Virginia Department of Agriculture and Consumer Services
Division of Consumer Protection
Office of Meat & Poultry Services
P.O. Box 1163
Richmond, Virginia 23218