



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Stager Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

WARNING LETTER

WL-CIN-13571-02

May 31, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dennis D. Hartong, Owner
738 Killinger Road
Clinton, OH 44216

Dear Mr. Hartong,

An inspection of your dairy farm operations located at 705 Killinger Road, Clinton, OH 44216 by Food and Drug Administration Investigators on April 23, 2002 confirmed that one cow sold by you for slaughter for human food was adulterated within the meaning of Section 402 (a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act).

USDA/FSIS analyses of tissues collected from the animal disclosed the presence of the following drug:

Identification of Animal	Drug	Level	Tolerance
31CTS/375	Penicillin	0.34ppm	0.05ppm

The tolerance level for penicillin is found in Title 21 Code of Federal Regulations Section 556. The presence of the drug, at levels above the tolerances, in edible tissue from the animal causes the food to be adulterated.

Moreover, the cow sold by you for slaughter for human food was adulterated pursuant to Section 402(a)(4) of the Act because it was "prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you held an animal which was ultimately offered for sale for slaughter as food under conditions which were so inadequate that medicated animals bearing possibly harmful drug residues were likely to enter the food supply. The investigator documented that you do not keep treatment records that identify the animals, dates of medication, drugs, dosages and pre-slaughter withdrawal times for the animals that you medicate.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to correct the violations may result in regulatory action such as seizure and/or injunction without further notice.

The violations listed above are not intended to be an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law. To avoid future illegal residue violations you should take precautions such as:

1. You should maintain records covering the medication history of the animals that you medicate. If the animal has been medicated, you should implement a system to withhold the animal from auction/slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue.
2. If you do not want to hold medicated animals but still wish to sell them, then you should not offer them for human food. You should clearly identify and sell them as medicated animals.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. You should be aware that it is not necessary for you to have personally shipped an animal in interstate commerce or to have medicated the animal yourself to be responsible for a violation of the Act. The fact that you offered an animal that was not free from illegal drug residues for sale to an auction that deals in food animals in interstate commerce is sufficient to hold you responsible for a violation of the Act.

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, has been taken, or will be taken to correct the violations and prevent the 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 addressed to Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237-3097, Attention: Stephen J. Rabe, Compliance Officer.

Sincerely



Henry L. Fielden
District Director
Cincinnati District Office