DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region 5267

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973)526-6010

WARNING LETTER

Certified Mail
Return Receipt Requested

March 8, 2001

Mr. Frank Carper
43 Brickyard Road
Cranbury, New Jersey 08512

File No.: 01-NWJ-19

Dear Mr. Carper:

An inspection of your facility, located in Cranbury, New Jersey, was conducted on October 24 & 27, 2000. The inspection was conducted to confirm that a horse purchased and sold by you on or about August 21, 2000, for slaughter for human food to [redacted] was in violation of Sections 402(a)(2)(C)(ii), 402(a)(4) and 501(a)(5) 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. On August 21, 2000, a horse you sold for slaughter for human food was sampled by the United States Department of Agriculture (USDA). The horse was identified by USDA laboratory report number 867549. The equine was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from the equine revealed streptomycin in the kidney tissue at 0.38 parts per million (ppm). Presently, the tolerance level for streptomycin in the edible tissue of equines is 0.0ppm, (Title 21, Code of Federal Regulations, Section 556).

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 inadequate, and medicated animals bearing possibly harmful drug residues are likely to enter the food supply. To avoid future legal actions, you should take the following measures:

1. Implement a system to identify the animals you purchase with records to establish traceability to the source of the animal.
2. Implement a system to determine, from the source of the animal, whether the animal has been mediated and with what drug(s).
3. If the animal has been medicated, implement a system to withhold the animal from slaughter for the appropriate period of time to deplete from edible tissue the potential hazardous residues of drugs. If you do not want to hold the medicated animal, then it should be clearly identified and sold as a medicated animal.

You caused the drug streptomycin, which was used to medicate the equine, to be adulterated within the meaning of Section 501(a)(5) of the Act. Streptomycin is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling.

In addition, USDA has reported the finding of illegal residues in two other equines sold by you and offered for slaughter for human food. These equines were sold on or about March 29 & 30, 2000, and were found to contain streptomycin residues of 0.59ppm and 0.71ppm. USDA and the Food and Drug Administration (FDA) notified you of these findings previously.

You were also notified of additional deficiencies with your practices in June 2000 by a list documented on an FDA-483, List of Inspectional Observations. During the recent inspection, you informed our investigator that you have made no attempt to correct the deficiencies. It is your responsibility to assure that your operations are in compliance with the law.

Failure to comply with the label instructions on a drug presents the possibility that illegal residues will occur and makes the drug unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

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

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

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 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. Your response should address each discrepancy brought to your attention during the inspection and in this letter. You should also include copies of any documentation demonstrating that corrections have been made.

Your reply should be sent to: U.S. Food & drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attention: Sarah A. Della Fave, Compliance Officer.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District