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BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo NY 14202

20 November 1996

WARNING LETTER BUF 97-5

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Mr. Lee Soule, Jr.
d/b/a Pete Soule & Sons
RD 2, Box 281
Hamilton, New York 13346

Dear Mr. Soule:

An inspection of your operation located in Munsville, New York, by Food and Drug Administration Investigator William P. Chilton, on 18 September 1996 and 31 October 1996, confirmed a cow identified with sale tag #517 and back tag 21HT2511 handled by you on or about 20 May 1996, and a cow identified with sale tag #738 and back tag #21HT2743 handled by you on or about 3 June 1996, and shipped for slaughter for human food to [REDACTED] were in violation of Section 402(a)(2)(D) of the Federal Food, Drug and Cosmetic Act.

USDA/FSIS analysis of tissues collected from the first cow disclosed the presence of the drugs Penicillin, at a level of .25 ppm in kidney tissue; Streptomycin, at a level of 1.5 ppm in kidney tissue; and Streptomycin, at a level of 1.2 ppm in liver tissue. Analysis of tissues collected from the second cow disclosed the presence of the drug Penicillin, at a level of .88 ppm in kidney tissue and a level of .10 ppm in liver tissue. A tolerance of 0.05 ppm has been established for residues of Penicillin, and a tolerance of 0.50 ppm has been established for residues of Streptomycin in edible tissues of cattle. The presence of these drugs at higher levels in edible tissues from cattle causes the food to be adulterated.

Our investigation also found you handled cattle under conditions which are so inadequate that medicated cattle bearing potentially harmful drug residues are likely to enter the food supply. For example, it is your policy not to accept medicated animals; however, you fail to determine from the previous owner or caretaker whether an animal has been medicated.

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 such as seizure and/or injunction, without further notice.



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The violations listed above are not intended to be an all inclusive list. It is your responsibility to assure your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces, or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Federal Food, Drug and Cosmetic Act. To avoid future illegal residue violations, you should take precautions such as:

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

You should be aware it is not necessary for you to have personally shipped an animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office, in writing, within 15 days of the specific steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, or to be taken, to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 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 corrections have been made.

Your reply should be directed to: Joseph H. Erdmann, Team Leader
U S Food and Drug Administration
P O Box 7197
250 South Clinton Street, Suite 601
Syracuse, New York 13261.

Sincerely,



E. Pitt Smith
District Director

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