DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
D1142B

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

January 29, 1997

Ref: 97-DAL-WL-#14

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. and Mrs. Sam Varner, Owners
Varner & Varner
Rt. 2, Box 74
Bristow, Oklahoma 74010

Dear Mr. and Mrs. Varner:

An investigation of your cattle order buyer/dealer operation on December 18, 1996, and January 9, 1997, confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), and you caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act. A food is adulterated if it bears or contains a new animal drug (or conversion product thereof) which is unsafe within the meaning of Section 512 of the Act (Section 402(a)(2)(D)).

On November 12, 1996, Varner & Varner delivered a spotted steer identified with back tag #73CE8520 along with [redacted] additional head of cattle to [redacted] on behalf of [redacted] (mispelled [redacted] on drive-in ticket). [redacted] The spotted steer bearing back tags #73CE8520 and #95099 was subsequently purchased and sold for slaughter as human food a[redacted] on November 22, 1996. USDA analysis (Laboratory Report #847376) of tissue samples collected from this animal identified the presence of sulfamethazine at 0.38 ppm in liver and 0.25 ppm in muscle. A tolerance of 0.1 ppm has been established for residues of sulfamethazine in the edible tissues of cattle (Title 21 Code of Federal Regulations 556.670). The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You do not have assurance, and make no attempt to gain the assurances from sellers, that animals for which you take possession as an order buyer in the name of a second party/owner and subsequently offer in the name of the second party/owner for sale for slaughter have not been medicated prior to the shipment to the slaughter facility. Your

firm was not able to identify the seller or source of the spotted steer delivered to MASI on November 12, 1996. Additionally, you do not have a system in place assuring that cattle treated with medication by Varner & Varner personnel, and whose edible tissues may contain unsafe drug residues, are withheld from delivery for sale for slaughter for human food. For example, you lack a system which identifies medicated animals and provides assurance that animals receiving medication are withdrawn from drugs for the required withdrawal period prior to offering them for sale for slaughter. You also lack drug treatment records identifying drugs administered, and the date and amount of administration.

You verified to the investigators that, although records are not maintained, it is the routine practice of Varner & Varner to medicate animals showing signs of illness with a variety of drugs. One of these drugs is Durvet Sustain III Sulfamethazine 32.1 gram Sustain Release Boluses carrying a 12 day withdrawal warning statement. You confirmed the spotted steer brought a sale price indicating the animal was sick, and therefore, it is likely the animal was administered the sulfamethazine boluses at Varner & Varner's cattle operation or at MASI while being temporarily held for a pending sale date. You also provided information indicating the injection sites present on the spotted steer may also have resulted from Varner & Varner personnel administering injections of the injectable drug Nuflor (florfenicol) requiring a 28 day withdrawal prior to slaughter. Food from animals held under such condition is adulterated.

You have adulterated the drug Sustain III Sulfamethazine Bolus within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug without following the withdrawal period (12 days) causes the drug to be unsafe within the meaning of Section 512(a)(1)(B).

The above is not intended to be an all-inclusive list of violations. It is your responsibility to assure that your operations are in compliance with the law. As a cattle order buyer/dealer operation taking possession of and marketing animals on the order of a second party/owner, you are frequently the individual(s) offering animals which may be adulterated for sale for introduction into interstate commerce. As such, you share the responsibility for violating the Federal Food, Drug and Cosmetic Act. 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 and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

A copy of this letter is being sent to Mr. [redacted] and Mr. [redacted] Owner of [redacted] They share in the responsibility for the residue in the animal offered for slaughter.

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 drugs; and

3) If the animal has been medicated, either by the seller or your buyer/dealer operation, implementing a control system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to James R. Lahar, Compliance Officer, at the above letterhead address.

Sincerely yours,

Sylvia G. Yates

FOR Joseph R. Baca
Dallas District Director

JRB:JRL:jab

cc: [redacted]