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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER

99-DT-15

September 17, 1999

Mr. Ralph Lettinga
President
Walnut Dale Farm
4309 14th Street
Wayland, MI 49348

Dear Mr. Lettinga:

An inspection of your dairy and feeder cattle operation, located at 4309 14th Street, Wayland, MI, was conducted on May 24-25, 1999 by Investigator William G. Nelson. The inspection confirmed that your firm offered bob veal calves for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, and you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

In January, August, and September 1998, you sold bob veal calves to [REDACTED]. Seven of these calves were sampled and tested at [REDACTED] by USDA/FSIS during routine tissue residue monitoring activities.

1. All seven were found with Sulfamethazine residue values from [REDACTED] ppm, a 0.1 ppm tolerance drug.
2. Six of the seven were found with Gentamycin residue values from [REDACTED] ppm, a zero tolerance drug.
3. One had a Sulfathiazole residue value of [REDACTED] ppm, a zero tolerance drug.
4. One had a Tetracycline residue value of [REDACTED] ppm, a zero tolerance drug.
5. One had a Streptomycin residue level of [REDACTED] ppm, a zero tolerance drug.

The presence of these drugs in edible tissues from these animals causes the food to be adulterated.

Our inspection also found that you had been holding bob veal calves under conditions so inadequate that diseased and/or medicated animals bearing potentially harmful drug residues were likely to enter the food supply. For example, your practice was to feed these calves throw away milk from medicated cows under treatment in your hospital barn. Furthermore, your system for housing, feeding, and delivering calves for slaughter lacked any means to identify specific animals. Such a system may have permitted identification and separation of those animals having received drugs, so they could be

withheld from sale for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions are adulterated.

You were adulterating the drugs that were being used within the meaning of Section 501(a)(5) of the Act when you failed to use them in conformance with their approved labeling. Your use of a drug in a species for which it is not approved, without following labeled withdrawal periods, etc. caused the drugs to be unsafe to use.

Mr. Kevin Lettinga, Vice President, described for Investigator Nelson, the operating procedures in place between January and October 1998. He speculated that the use of "throw away milk" led to the drug residues found in the USDA/FSIS samples. Kevin Lettinga further stated that since October 1, 1998, the bob veal portion of your operation has been discontinued.

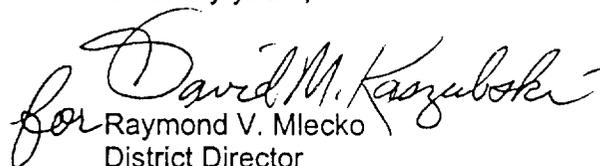
Investigator Nelson reminded Kevin Lettinga that our inspection was the result of the multiple drug tissue residues found by USDA. Let me remind you it is your responsibility to assure that when your farm sells any medicated animals the buyer must be alerted to the fact that an animal had been treated with a drug and had not yet achieved the necessary withdrawal time. When selling a treated animal you should never assume it will not go for slaughter. For example an animal sold as a feeder calf could be purchased by a slaughter facility and slaughtered the next day. Finally, it is your responsibility to work with your veterinarian to determine the appropriate withdrawal times for meat and milk for directly treated animals and for animals that had been fed milk from treated cows.

The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your firm is in full compliance with the Act and regulations promulgated thereunder.

We request that you take prompt action to assure these deviations do not reoccur. If you resume the bob veal operations on your farm, the problems described must first be corrected. Failure to make prompt corrections may result in regulatory action without further notice, such as seizure and/or injunction.

If you have any additional response to this letter it should be directed to this office to the attention of Mr. Melvin O. Robinson, Acting Compliance Officer. (313) 226-6260 Extension 178

Sincerely yours,


for Raymond V. Mlecko
District Director
Detroit District