



December 20, 1999

**WARNING LETTER
CIN-WL-00-2-1**

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

James R. Cooksey
9129 E. Ringgold Fairfield Rd.
Circleville, OH 43113

Dear Mr. Cooksey:

An investigation by the U.S. Food and Drug Administration (FDA) documented that a beef cow (steer) identified with tag number 819, was offered for sale for slaughter by [REDACTED], at the [REDACTED], on 6/26/99, and was found to contain an illegal drug residue. Laboratory analysis of urine sample #14008, collected on 6/24/99, shows phenylbutazone levels greater than 500 ppb (parts per billion) in the urine of the referenced animal. These levels yield a calculated level of 72 to 180 ppb in the edible tissue (muscle), a level evaluated and determined to be of significant human health concern. There is no tolerance established for this drug in cows intended for slaughter as human food. This cow was offered for slaughter as food in violation of sections 402(a)(2)(C)(ii), 402(a)(4) and section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act).

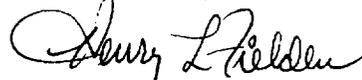
We understand that Dr. [REDACTED] DVM, treated this animal with phenylbutazone oral paste, on June 7, 1999. We are also aware that Dr. [REDACTED] advised you that the required withdrawal time for this drug was 10 to 14 days prior to slaughter. Based on our evaluation, this is not an adequate withdrawal time for this drug when used in food producing animals. We have already advised Dr. [REDACTED] of this violation.

However, you as the producer of this food-animal also have responsibility to assure that the animals that you sell are free from drug residues. You should take whatever steps are necessary to determine whether any drugs supplied to your animals pose a significant risk of potentially harmful drug residues. This includes either withholding the animal for a withdrawal period that is supported by appropriate scientific information, or taking whatever measures are necessary to assure that the animal and its food products do not enter the human food supply.

Please notify this office within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct the noted violations and to prevent recurrence of similar violations in the future. Failure to promptly implement adequate corrections may result in further regulatory action without prior notice, such as seizure and/or injunction.

Your response should be directed to the U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237-3097, Attention: Charles S. Price, Compliance Officer. If you have any questions, you may direct these to Mr. Price at (513) 679-2700 extension 165.

Sincerely,

A handwritten signature in cursive script, appearing to read "Henry L. Fielden".

Henry L. Fielden
District Director
Cincinnati District