



January 13, 2000

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

WARNING LETTER  
CHI-10-00

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Donald E. Welge, President  
Gilster-Mary Lee Corporation  
1037 State Street  
Chester, IL 62233

Dear Mr. Welge:

On June 17, 1999, an investigator from the Food and Drug Administration (FDA) collected a sample of "Kroger\*\*Baking Mix Original\*\* NET WT 40 OZ (2 LB 8 OZ)\*\* Sell by JUN1700G\*\*" from your plant. The sample was analyzed by our Southeast Regional Laboratory in Atlanta, Georgia, and found the level of iron in the product to contain 31.5 % (check analysis 40.0%) of the label declared level - 15%.

The baking mix is adulterated within the meaning of Section 402(b)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) in that a valuable constituent (iron) has been in whole or in part omitted from the product. The baking mix is misbranded within the meaning of Section 403(a)(1) of the Act in that the label declared level of iron (DV 15%) is false and misleading.

You should take prompt action to correct these violations. 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 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Paul Boehmer, Compliance Officer.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director