



May 23, 1990

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive S.E.  
P.O. Box 3012  
Bothell, WA 98041-3012

In reply refer to: SEA 90-24

Telephone: 206-486-8788  
FAX: 206-483-4996

Lee Stiles, President  
Ruth Ashbrook Bakery  
Division of Gai's, Incorporated  
1416 Tenth Avenue  
Seattle, Washington 98122

REGULATORY LETTER

Dear Mr. Stiles:

Please reference a Notice of Adverse Findings letter dated February 14, 1990, issued to your attention, and your reply dated March 6, 1990.

As you were previously advised, a sample of your product "RAINIER FARMS HOMESTYLE EUROPEAN SWEET WHEAT BREAD NET WT 24 OZ\*\*\*\*" was collected and the labeling reviewed. The product was found to be misbranded in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and associated labeling regulations found in the Code of Federal Regulations, Title 21, as follows:

<u>SECTION</u>	<u>BRIEF DESCRIPTION</u>
403(a)	<p>The heart symbol and accompanying declaration "for health and fitness" falsely represents and suggests that this product will prevent, mitigate, or cure heart or artery disease or conditions.</p> <p>The label statement "vitamins B<sub>1</sub>, B<sub>2</sub>, Niacin and Iron" falsely represents that this food is a significant source of these four nutrients. Statements that a food is a significant source of a nutrient may not be made unless the nutrient is present in the food at a level equal to or in excess of 10% of the U.S. RDA in a serving.</p> <p>The statement suggesting a geographical origin of the food as European is false and misleading for a product manufactured in Seattle, Washington.</p>

We wish to point out that, when the label is revised to correct the above violations, the following corrections should also be made:

LEE STILES, PRESIDENT  
RUTH ASHBROOK BAKERY DIVISION OF GAI'S, INC.  
PAGE 2

1. Under nutrition information, the serving size declaration should be on the basis of "2 slices" with all nutrition information based on that serving size.
2. Under the cholesterol declaration, the term "total" which appears between the word "their" and "dietary" should be deleted.
3. The correct caption is "Percentage of U.S. Recommended Daily Allowances (U.S. RDA)" rather than "Percentages of U.S. Recommended Daily Allowance."

We request that you take prompt action to correct these violations. If such action is not taken, the Food and Drug Administration is prepared to invoke the regulatory sanctions under the law. These include seizure and/or injunction.

Please notify us within ten (10) days of the steps you have taken to correct the violations. You should review your product line to assure that similar violations are corrected.

Your response should be directed to:

Albert P. Duzenack  
Compliance Officer  
Food and Drug Administration  
22201 23rd Drive  
Post Office Box 3012  
Bothell, Washington 98021-3012

Sincerely,

David L. Chesney  
Acting District Director

