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July 2, 2004

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)  
5100 Paint Branch Parkway  
College Park, Maryland 20740  
Reference phone #301-436-2373

AUG 12 2004

Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

**(1) Name and Address of distributor:**

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

**(2) Statements:**

**Gentle Fibers™** provides: Dietary fibers preferred by Lactobacilli and Bifidobacteria for fermentation and replication, which encourages healthy intestinal microflora balance; A spectrum of naturally occurring flavonoids: hesperidin, naringen, limocitrol and others. Both soluble and insoluble fibers for bowel function and glycemic balance: Insoluble: Cellulose and Hemicellulose; Soluble: Pectin and Mucilage; Lignans from flax seed meal. Lignans have been shown to support healthy cell replication and cardiovascular function; IP6 (Inositol Hexophosphate), from rice bran, promotes normal cell replication and provides cell protection. Bitter flavor notes of **Gentle Fibers™** are due to the flavonoids from citrus fruits. These flavonoids are powerful antioxidants providing beneficial effects on anti-inflammatory pathways and the body's detoxification mechanisms.

Note: Do not take it along with multi-vitamin/ mineral supplements or medications. People allergic to citrus should not use this product.

**(3) Name of the dietary ingredient(s) if not provided in the text of the statement:**

Flax Seed Meal, Rice Bran, Orange Pulp and Peel, Grapefruit Pulp and Peel, Lemon Peel

**(4) Name of the dietary supplement(s):**

Gentle Fibers

**(5) The following disclaimer appears on the label in bold:**

**These statements have not been evaluated by the Food and Drug Administration.  
This product is not intended to diagnose, treat, cure or prevent any disease.**

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of the nutrients.

Respectfully submitted,



Peilin Guo, MS, RD

Vice President of Functional Foods and Clinical Research

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