

# MANNATECH

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May 9, 2005

Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway.  
College Park, MD 20740

Re: Statement of Nutritional Support Notification – GI-Zyme

Dear Sir or Madam:

In accordance with 21 U.S.C. § 343 (r) and 21 CFR § 101.93, Mannatech Incorporated, 600 S. Royal Lane, Ste 200, Coppell, TX 75019, hereby submits an original and two copies of it's notification within 30 days of first marketing its product with the statements presented below:

Supplement Brand Name: GI-Zyme

Supplement Ingredients: See attached SF box.

Text of Statements of Nutritional Support:

1. Can help improve the level of digestion and help assure that the maximum level of nutrient absorption is obtained.
2. Assists in breaking down proteins, fats and carbohydrates.
3. Has a wide range of pH activity (pH 1.0 – 8.0).
4. Helps reduce the daily stool weight and total daily fecal excretion.
5. Contains amylase, lactase and malt diastase that helps to reduce the toxicity associated with gluten proteins.

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600 S. Royal Lane, Suite 200, Coppell, TX 75019

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Mannatech Incorporated certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the Dietary Supplement Health and Education Act (DSHEA); and that the information contained in this notice is complete and accurate.

Yours truly,

A handwritten signature in cursive script that reads "Dennis R. Sparkman". The signature is written in black ink and is positioned above the typed name and title.

Dennis R. Sparkman, Ph.D.  
Executive Director of Global Regulatory Affairs  
972-471-7368  
dsparkman@mannatech.com

Enclosure: GI-Zyme SF box.

