



**ENZYMATIC THERAPY**  
INCORPORATED

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**INTEGRATIVE THERAPEUTICS INC.™**  
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Tyler Encapsulations + Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 + F: 503.582.0467

**ENZYMATIC THERAPY®**  
&  
**PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328  
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P: 920.469.9099 + F: 920.469.4418 (Phyto)

July 13, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

JUL 2 2004

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Fiber Fusion™	Psyllium husk has benefits that extend beyond digestive health. It also supports healthy serum lipid levels that are already within normal limits, healthy blood sugar metabolism that is already within normal limits, healthy blood pressure that is already within normal limits, healthy immune function and intestinal microflora.*	Psyllium (Plantago ovata) Husk

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_  
Robert Doster

Title: Senior Vice President of Scientific Affairs

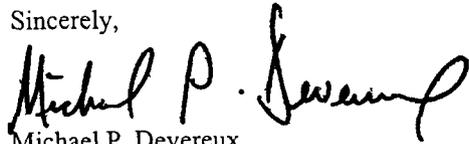
Date: 7-13-04

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If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael P. Devereux  
Chief Financial Officer