



ENZYMATIC THERAPY
INCORPORATED

What *Better* feels like.™

INTEGRATIVE THERAPEUTICS INC.™
NF Formulas ♦ PhytoPharmica
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
P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)
P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

1202 5 MAY 23 P2:37

April 26, 2005

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

MAY - 3 2005

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.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Probiotic Pearls™	Probiotics play a crucial role in supporting your digestive health, which is connected to every single function of your body.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

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 C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 4-26-05

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

Sincerely,

Michael P. Devereux
Chief Financial Officer

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Probiotic Pearls™	They are the "good" bacteria, also known as microflora, that keep your digestive system running smoothly by digesting food and processing wastes.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

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 C. Doster
Robert C. Doster
Title: Senior Vice President of Scientific Affairs

Date: 4-26-05

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Sincerely,

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Probiotic Pearls™	Studies have shown that probiotics can promote a healthy urinary tract.*	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum

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 C. Doster
Title: Senior Vice President of Scientific Affairs

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