



Enzymatic Therapy

# 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)

October 22, 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

RE: Label Claims/Disclaimers

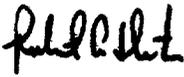
Dear Sir or Madam:

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
Prenatal Forte	This complete, high potency, daily multivitamin-mineral delivers optimal nutritional support to pregnant or nursing mothers throughout the day.* In addition to providing a comprehensive nutritional foundation, Prenatal Forte also includes digestive plant enzymes and classic herbs such as red raspberry leaf, yellow dock, cranberry, dandelion and stinging nettle, as well as papaya and probiotics to help with the digestive concerns often associated with pregnancy and nursing.*	Vitamin A (as vitamin A acetate and 50% as beta-carotene; Betatene® natural mixed carotenoids), Vitamin C (as calcium ascorbate), Vitamin D (as ergocalciferol), Vitamin E (as dl-alpha-tocopheryl acetate), Vitamin K (as phytonadione), Thiamin (as thiamin HCl), Riboflavin, Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Biotin, Pantothenic Acid (as calcium pantothenate), Calcium (as calcium carbonate, citrate, and ascorbate), Iron (as iron citrate), Iodine (from kelp), Magnesium (as magnesium oxide and citrate), Zinc (as zinc citrate), Chromium (as chromium amino acid chelate), Potassium (as potassium citrate), Citrus Bioflavonoids Complex, L-Glutamic acid hydrochloride, Soy lecithin, Alfalfa leaf (Medicago sativa), Raspberry leaf (Rubus idaeus), Yellow Dock root (Rumex crispus), Cranberry fruit (Vaccinium macrocarpon), Dandelion root (Taraxacum officinale), Papaya leaf (Carica papaya), Stinging Nettle leaf (Urtica dioica), Choline (as choline bitartrate), Inositol, Lactobacillus acidophilus, PhytZyme enzyme blend – Amylase, Cellulase, Glucoamylase, Invertase, Lipase, Pectinase with Phytase, Protease, and Lactase, Hesperidin, Rutin, Boron (as boron citrate)

975 0162 LET 14853

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.

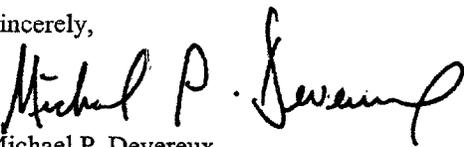
By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date 10/22/04

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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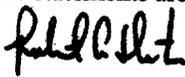
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Prenatal Forte	Vitamins, minerals, and herbs for daily energy support and essential nutrition.*	Vitamin A (as vitamin A acetate and 50% as beta-carotene; Betatene® natural mixed carotenoids), Vitamin C (as calcium ascorbate), Vitamin D (as ergocalciferol), Vitamin E (as dl-alpha-tocopheryl acetate), Vitamin K (as phytonadione), Thiamin (as thiamin HCl), Riboflavin, Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Biotin, Pantothenic Acid (as calcium pantothenate), Calcium (as calcium carbonate, citrate, and ascorbate), Iron (as iron citrate), Iodine (from kelp), Magnesium (as magnesium oxide and citrate), Zinc (as zinc citrate), Chromium (as chromium amino acid chelate), Potassium (as potassium citrate), Citrus Bioflavonoids Complex, L-Glutamic acid hydrochloride, Soy lecithin, Alfalfa leaf (Medicago sativa), Raspberry leaf (Rubus idaeus), Yellow Dock root (Rumex crispus), Cranberry fruit (Vaccinium macrocarpon), Dandelion root (Taraxacum officinale), Papaya leaf (Carica papaya), Stinging Nettle leaf (Urtica dioica), Choline (as choline bitartrate), Inositol, Lactobacillus acidophilus, PhytZyme enzyme blend – Amylase, Cellulase, Glucoamylase, Invertase, Lipase, Pectinase with Phytase, Protease, and Lactase, Hesperidin, Rutin, Boron (as boron citrate)

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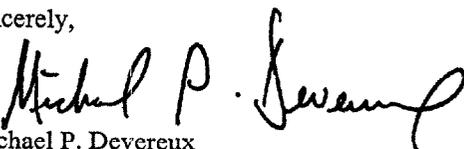
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