



ENZYMATIC THERAPY

INCORPORATED

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P: 503.582.8386 • F: 503.582.0467

ENZYMATIC THERAPY®
&
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328
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March 25, 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

MAR 30 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
PMS Symptom Free®*	Especially useful when PMS symptoms are multiple vs. singular – i.e., mood changes, breast tenderness, water retention, fatigue vs. cramps alone.*	Vitamin D (as cholecalciferol), Calcium (as calcium citrate and calcium carbonate), Iodine (as potassium iodide), Magnesium (as magnesium aspartate), Chaste Tree (Vitex agnus-castus) Berry Extract, Diindolymethane (DIM) (as Indolplex® brand blend)

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: 3/25/05

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

Sincerely,
Michael P. Devereux
Michael P. Devereux
Chief Financial Officer

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