



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)

1053 5 OCT 28 P2:21

October 18, 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

24

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
Relax-O-Zyme®*	Provides natural relaxation and stress relief.*	Vitamin D (as cholecalciferol), Niacin (as niacinamide and niacin), Vitamin B6 (as pyridoxine HCl), Calcium (as calcium citrate), Magnesium (as magnesium oxide and magnesium gluconate), Zinc (as zinc chelate), Valerian (Valeriana officinalis) Root, Chamomile (Matricaria recutita) Flower Extract, Passionflower (Passiflora incarnate) Leaf, Hops (Humulus lupulus) Flower Extract, Evening Primrose (Oenothera biennis) Seed Oil

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
Robert Doster
Title: Senior Vice President of Scientific Affairs

Date: 10/18/05

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

975 0162 LET 16902



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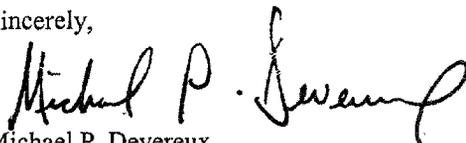
PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Relax-O-Zyme®*	Reduces nervous tension and irritability.*	Vitamin D (as cholecalciferol), Niacin (as niacinamide and niacin), Vitamin B6 (as pyridoxine HCl), Calcium (as calcium citrate), Magnesium (as magnesium oxide and magnesium gluconate), Zinc (as zinc chelate), Valerian (Valeriana officinalis) Root, Chamomile (Matricaria recutita) Flower Extract, Passionflower (Passiflora incarnate) Leaf, Hops (Humulus lupulus) Flower Extract, Evening Primrose (Oenothera biennis) Seed Oil

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