



**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)

August 3, 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.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Lypotropic Complex™	Combines phytonutrients and bile salts with essential vitamins and minerals to provide comprehensive nutritional support for hepatobiliary function.*	Vitamin B6 (as Pyridoxine Hydrochloride), Folic Acid, Vitamin B12 (as Cyanocobalamin), Magnesium (as Magnesium Aspartate, Oxide), L-Methionine, Choline (as Choline Bitartrate), Black Radish Root (Raphanus sativus-niger), Beet Leaf (Beta vulgaris), Inositol, Fringe Tree Root Bark (Chionanthus virginicus), Dandelion Root (Taraxacum officinale), Milk Thistle Seed (Silybum marianum), Celandine Aerial Parts Extract (Chelidonium majus) (2.3% Alkaloids), Ox Bile Extract, Milk Thistle Seed Extract (Silybum marianum ) (90% Silymarin)

975 0162 LET 14491

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: 8/3/04

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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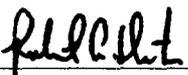
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Lypotropic Complex™	Silymarin, which has been researched for its antioxidant effects, has also been reported to act as a methyl donor.*	Milk Thistle Seed Extract (Silybum marianum ) (90% Silymarin)

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.

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