

# Enzymatic Therapy

NATURAL MEDICINES®

March 11, 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>
VariCare®	The patented Phytosome™ technology, which combines one part standardized gotu kola extract with two parts phosphatidylcholine, dramatically improves absorption. Research indicates Phytosomes are absorbed more effectively than non-Phytosome products.*	Butcher's Broom (Ruscus aculeatus) Root and Rhizome Extract, Horse Chestnut (aesculus hippocastanum) Seed Extract, Gotu Kola (Centella asiatica) Leaf Phytosome™

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: 3/11/04

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www.enzy.com

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VariCare 1e (BW)

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

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux  
Chief Financial Officer