

August 8, 2002

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Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

Label Claims/Disclaimers RE:

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Grape Seed (PCO) Phytosome™	Grape (Vitis vinifera) Seed Phytosome™	Grape Seed (PCO) Phytosome™ (50 or 100 mg) has been enhanced by a special, patented Phytosome™ process that dramatically increases absorbability.*

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: \$/8/02

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

Sincerely, . Nevern Michael P. Devereux

975 0162 LET 10883

825 Challenger Drive Green Bay, WI 54311-8328 Ph: 920-469-1313 Fax: 888-570-6460 www.enzy.com

Grape Seed (PCO) Phytosome 3e

Chief Financial Officer

81523



August 9, 2002

RORNED AUG 1 4 2002 ·BY:

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

RE: Label Claims/Disclaimers

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Grape Seed (PCO) Phytosome™	Grape (Vitis vinifera) Seed Phytosome™	The result is improved biological activity and 3-7 times more absorption than non- Phytosomes.*

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: 8/9/02

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

Sincerely,

Chief Financial Officer

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Grape Seed (PCO) Phytosome 4e