

May 17, 2002

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

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	<u>DIETARY</u> <u>INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Hawthorn Phytosome™	Hawthorn (Crataegus oxyacantha) Leaf and Flower Phytosome™	Hawthorn Phytosome™ combines one part hawthorn (Crataegus oxyacantha) extract (standardized to contain 1.8% vitexin-2′-rhamnoside) and two parts of phosphatidylcholine (the chief component of lecithin) to form a PHYTOSOME™. The result of this patented process is improved absorption and biological activity*

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.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5-17-02

Chief Financial Officer

Hawthorn Phytosome 2 e

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely, 825 Challenger Drive

Green Bay, WI 54311-8328

Ph. 920-469-1313

Fax. 888-570-6460

www.enzy.com

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