

September 7, 2002

7503

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		DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Concentrate™	DMAE, Phosphatidylserine, N-acetylcysteine (NAC), Taurine, L-Theanine	Phosphatidylserine supports brain health at a cellular level.*

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.

Title: Director of Product Development

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

975 0162 LET 10997

Sincerely,

Michael P. Devereux Chief Financial Officer

825 Challenger Drive Green Bay, WI 54311-8328

