

July 24, 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:

JUL 2 9 2002

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.	Pro-Gest-Ade™	Niacinamide, Betaine HCl, L-Glutamic-Acid HCl, Bromelain, Papain, Mylase, Mycozyme, Ox bile Extract, Pancreas Extract	Pro-Gest-Ade's enzymes support healthy digestion- especially protein and fat digestion.*

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

7/24/02 Date:

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

Sincerely,

Jeven Michael P. Devereux

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

**Chief Financial Officer** 

Pro-Gest-Ade 1e



July 25, 2002

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RE: Label Claims/Disclaimers

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Pro-Gest-Ade™	Niacinamide, Betaine HCI, L-Glutamic-Acid HCI, Bromelain, Papain, Mylase, Mycozyme, Ox bile Extract, Pancreas Extract	It also supports healthy gastric (or stomach) acidity for proper digestion and subsequent nutrient absorption.*

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: 7/25/02

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

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

Michael P. Devereux Chief Financial Officer

Pro-Gest-Ade 2e