

April 9, 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

CITE FF ----APR 1 6 2002 BY:

Label Claims/Disclaimers RE:

Dear Sir/Madam:

This letter is to notify you that PhytoPharmica 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.

50212

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<b>STATEMENTS</b>
PhytoPharmica	Flush-Free Niacin	Niacin	Maintains healthy cholesterol levels that are already within the normal range.

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: 4/9/02

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

Michael P. Devereux **Chief Financial Officer** 

825 CHALLENGER DRIVE 975 0162 LET 9902 GREEN BAY, WI 54311-8328 920-469-9099 TOLL FREE 800-553-2370 FAX 920-469-4418 FAX TOLL FREE 888-311-5657 WWW, PHYTOPHARMICA.COM

Flush-Free Niacin. 1p v2