



INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.8386 F: 503.582.0467

**ENZYMATIC THERAPY®
&
PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328
P: 920.469.1313 F: 888.570.6460 (Enzymatic)
P: 920.469.9099 F: 920.469.4418 (Phyto)

ENZYMATIC THERAPY

What **Better** feels like™

January 5, 2006

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	There have been several clinical studies for natto for bone support.*	Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menoquinone -7)

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
Robert C. Doster
Title: Senior Vice President of Scientific Affairs

Date: 1-5-06

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

Sincerely,
Michael P. Devereux
Michael P. Devereux
Chief Operations Officer

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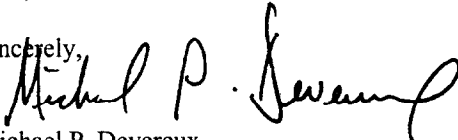
PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	Japanese researchers compared serum levels of vitamin K1 and vitamin K2 in two groups of women. The levels of K1 were virtually identical in both groups, yet serum levels of vitamin K2 were twice as high in the second group of women, who also experienced more significant support for bone health than the first group.*	Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menoquinone -7)

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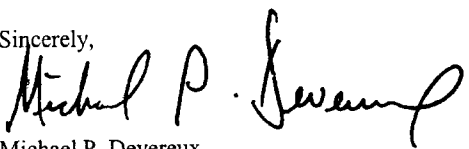
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	The menaquinone-7 levels of Japanese women living in Tokyo (where Natto K2 consumption is high), Japanese women living in Hiroshima (where Natto K2 consumption is lower) and women living in Great Britain (where Natto K2 consumption is almost non-existent) were compared. The Tokyo women had vitamin K2 levels of 5.26 ng/ml; the Hiroshima women had 1.22 ng/ml; and the British women had only 0.37 ng/ml of menaquinone-7/vitamin K2 in their bloodstream. The authors found that the women who had the highest levels of menaquinone experienced the greatest support for bone health.*	Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone -7)

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