



ENZYMATIC THERAPY
INCORPORATED

*What **Better** feels like.™*

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)

April 25, 2004

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

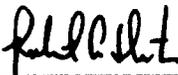
RE. Label Claims/Disclaimers

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.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Simple Energy™*	The standardized Rhodiola rosea root extract in this formula contains the phytochemicals rosavin and salidroside, that support mental and physical energy, nervous system health, and promote mental well-being.*	Rhodiola (Rhodiola rosea) Root Extract standardized to contain 3% rosavins and 1% salidroside

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 Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/25/04

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

Sincerely,


Michael P. Devereux
Chief Financial Officer

97S 0162 LET 141049



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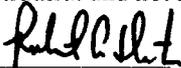
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Simple Energy™*	Current research has focused on Rhodiola rosea's effect on brain transmitters. Studies have shown that Rhodiola rosea extract supports the balance of various neurotransmitters such as norepinephrine, dopamine, and serotonin in the central nervous system.*	Rhodiola (Rhodiola rosea) Root Extract standardized to contain 3% rosavins and 1% salidroside

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.

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Date: 4/25/04

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April 26, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Simple Energy™*	In a double-blind crossover study, the effects of Rhodiola rosea extract on fatigue during the night duty was investigated on 56 healthy physicians. The effect was measured using tests that gauged mental fatigue involving complex perception and cognitive functions, tested before and after night duty. Significant improvements in perception and cognitive functions were observed in the group taking the Rhodiola rosea extract.* The results indicate that Rhodiola rosea extract can reduce general fatigue and increase mental physical energy under stressful conditions.*	Rhodiola (Rhodiola rosea) Root Extract standardized to contain 3% rosavins and 1% salidroside

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 Doster
 Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/26/04

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

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux
Chief Financial Officer



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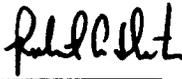
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Simple Energy™*	Herbal support for energy without side effects associated with other herbal products*	Rhodiola (Rhodiola rosea) Root Extract standardized to contain 3% rosavins and 1% salidoside

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