

Enzymatic Therapy

NATURAL MEDICINES®

November 5, 2003

8962 03 REC 10 NOV 19 2003 P2:10

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

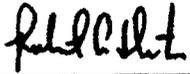
RE: Label Claims/Disclaimers

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 Cleanse* Laxative Formula | With Enzymatic Therapy's Simple Cleanse there is no depletion of vital vitamins, minerals, and enzymes that can leave users feeling drained and fatigued.* | Magnesium Hydroxide, Proprietary Mucilage Blend slippery elm bark, marshmallow root extract and fenugreek seed extract, Proprietary Soothing Blend peppermint leaf, fennel seed and ginger rhizome extract |

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: 11/5/03

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Green Bay, WI 54311-8328
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www.enzy.com

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Simple Cleanse Laxative Formula 39e

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 that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux
Chief Financial Officer