

# Enzymatic Therapy

NATURAL MEDICINES®

October 12, 2003

Mr. Robert Moore  
Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RECEIVED  
NOV - 5 2003

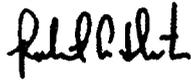
RE: Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor 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. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Simple Cleanse* Laxative Formula	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	As part of Simple Cleanse intestinal cleansing formula, a gentle easy-to-use intestinal detoxification method, Laxative Formula works with Fiber Formula to bind toxins and cleanse the intestines.*

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: 10/12/03

97S 0162

LET 13245

825 Challenger Drive

Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Simple Cleanse Laxative Formula 26e

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

# Enzymatic Therapy

NATURAL MEDICINES®

October 12, 2003

Mr. Robert Moore  
Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

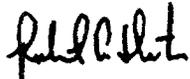
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Enzymatic Therapy, Inc.	Simple Cleanse* Laxative Formula	Magnesium Hydroxide, Proprietary Mucilage Blend slippery elm bark, marshmallow root extract and fenugreek seed extract, Proprietary Soothing Blend peppermint leaf, fennel seed and ginger rhizome extract	Laxative Formula is designed to gently loosen built-up substances on the intestinal wall and enhance the transit time of intestinal substances.*

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: 10/12/03

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

Simple Cleanse Laxative Formula 27c

# Enzymatic Therapy

NATURAL MEDICINES®

October 13, 2003

Mr. Robert Moore  
Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

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Enzymatic Therapy, Inc.	Simple Cleanse* Laxative Formula	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	Laxative Formula gently but effectively cleanses the intestinal surfaces and promotes bowel function without the use of harsh, stimulant laxatives, such as senna and cascara.* These laxatives chemically stimulate the intestines. If used on a routine basis, the bowels can become dependent on them and lose the built-in reflexes that normally help the bowels function. In contrast, Laxative Formula works with the body's own elimination processes to safely promote bowel movements.*

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: 10/13/03

Simple Cleanse Laxative Formula 28e

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com



# Enzymatic Therapy

NATURAL MEDICINES®

October 14, 2003

Mr. Robert Moore  
Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

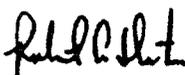
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Enzymatic Therapy, Inc.	Simple Cleanse* Laxative Formula	Magnesium Hydroxide, Proprietary Mucilage Blend slippery elm bark, marshmallow root extract and fenugreek seed extract, Proprietary Soothing Blend peppermint leaf, fennel seed and ginger rhizome extract	Magnesium hydroxide is an osmotic laxative that draws water into the intestinal lumen.* Fecal matter inside the intestines softens and swells, which stretches the intestinal wall and stimulates peristalsis.* Research has shown that magnesium hydroxide increases the number of bowel movements, increases percentage of stool water, and increases stool volume.*

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

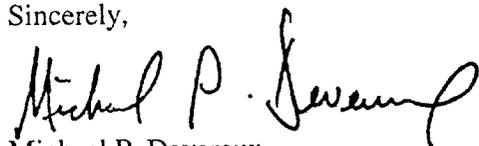
Date: 10/14/03

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

Simple Cleanse Laxative Formula 29e

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

# Enzymatic Therapy

NATURAL MEDICINES®

October 15, 2003

Mr. Robert Moore  
Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

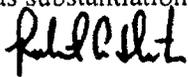
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Enzymatic Therapy, Inc.	Simple Cleanse* Laxative Formula	Magnesium Hydroxide, Proprietary Mucilage Blend slippery elm bark, marshmallow root extract and fenugreek seed extract, Proprietary Soothing Blend peppermint leaf, fennel seed and ginger rhizome extract	Slippery elm (Ulmus rubra) bark has antioxidant effects and has been studied for its support of bowel health.*

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: 10/15/03

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

Simple Cleanse Laxative Formula 30e

# Enzymatic Therapy

NATURAL MEDICINES®

October 15, 2003

Mr. Robert Moore  
Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

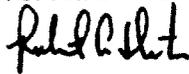
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I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.



By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/15/03

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

Simple Cleanse Laxative Formula 31e

# Enzymatic Therapy

NATURAL MEDICINES®

October 15, 2003

Mr. Robert Moore  
Office of Nutritional Products, Labeling &  
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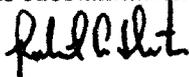
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I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

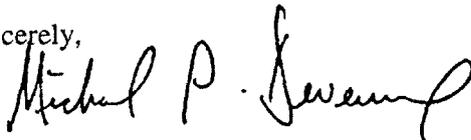
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/15/03

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

Simple Cleanse Laxative Formula 32e

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

# Enzymatic Therapy

NATURAL MEDICINES®

October 16, 2003

Mr. Robert Moore  
Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

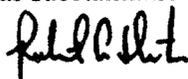
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I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.



By: \_\_\_\_\_

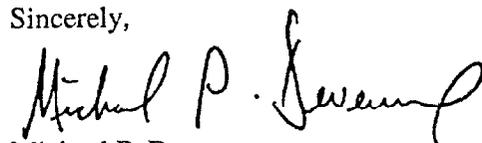
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/16/03

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

Simple Cleanse Laxative Formula 33e

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.ency.com

# Enzymatic Therapy

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October 16, 2003

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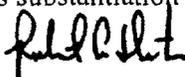
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I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.



By: \_\_\_\_\_

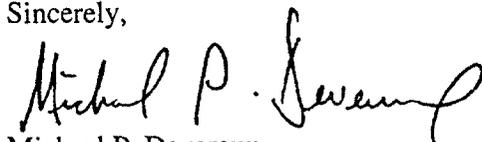
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/16/03

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

Simple Cleanse Laxative Formula 34e

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

# Enzymatic Therapy

NATURAL MEDICINES\*

October 16, 2003

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Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

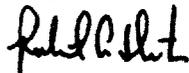
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Enzymatic Therapy, Inc.	Simple Cleanse* Laxative Formula	Magnesium Hydroxide, Proprietary Mucilage Blend slippery elm bark, marshmallow root extract and fenugreek seed extract, Proprietary Soothing Blend peppermint leaf, fennel seed and ginger rhizome extract	Use of peppermint has been clinically studied for its support of gastrointestinal motility and support of healthy balanced intestinal flora.*

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: \_\_\_\_\_

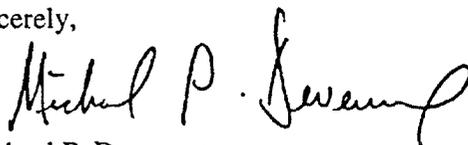
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/16/03

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

Simple Cleanse Laxative Formula 35e

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

# Enzymatic Therapy

NATURAL MEDICINES®

October 17, 2003

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Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

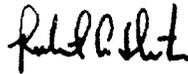
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I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.



By: \_\_\_\_\_

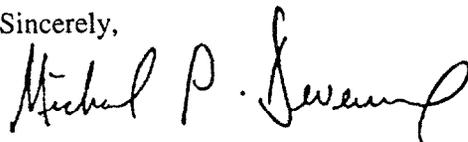
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/17/03

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Sincerely,



Michael P. Devereux  
Chief Financial Officer

Simple Cleanse Laxative Formula 36e

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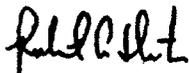
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I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

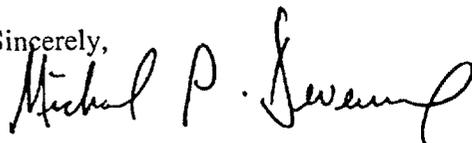
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/17/03

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Michael P. Devereux  
Chief Financial Officer

Simple Cleanse Laxative Formula 37e

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Fax: 888-570-6460

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# Enzymatic Therapy

NATURAL MEDICINES®

October 18, 2003

Mr. Robert Moore  
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5100 Paint Branch Parkway  
College Park, MD 20740

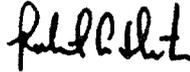
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I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.



By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/18/03

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

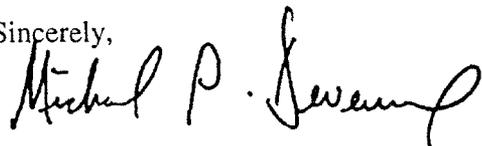
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If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

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