



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)

2157 11-17-04 10:12

November 17, 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

NOV 18 2004

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
Laxative-3 Blend™	Promotes safe, comfortable bowel elimination.*	Magnesium Hydroxide, Proprietary Mucilage Blend: slippery elm (<i>Ulmus rubra</i>) bark, marshmallow (<i>Althaea officinalis</i>) root extract and fenugreek (<i>Trigonella foenum-graecum</i>) seed extract, Proprietary Soothing Blend: peppermint (<i>Mentha x piperita</i>) leaf, fennel (<i>Foeniculum vulgare</i>) seed and ginger (<i>Zingiber officinale</i>) 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*
Robert Doster
Title: Senior Vice President of Scientific Affairs
Date: 11-17-04

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 Financial Officer

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Laxative-3 Blend™	Laxative-3 Blend is the gentle, triple-action way to support comfortable bowel elimination...safely, effectively and naturally.*	Magnesium Hydroxide, Proprietary Mucilage Blend: slippery elm (Ulmus rubra) bark, marshmallow (Althaea officinalis) root extract and fenugreek (Trigonella foenum-graecum) seed extract, Proprietary Soothing Blend: peppermint (Mentha x piperita) leaf, fennel (Foeniculum vulgare) seed and ginger (Zingiber officinale) rhizome extract

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Laxative-3 Blend™	It's "triple targeted support" ensuring worry-free regularity for occasional constipation.*	Magnesium Hydroxide, Proprietary Mucilage Blend: slippery elm (<i>Ulmus rubra</i>) bark, marshmallow (<i>Althaea officinalis</i>) root extract and fenugreek (<i>Trigonella foenum-graecum</i>) seed extract, Proprietary Soothing Blend: peppermint (<i>Mentha x piperita</i>) leaf, fennel (<i>Foeniculum vulgare</i>) seed and ginger (<i>Zingiber officinale</i>) rhizome extract

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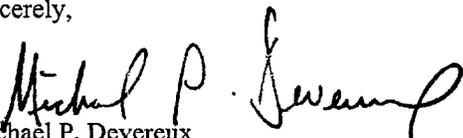
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Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11-18-04

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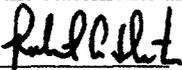
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Laxative-3 Blend™	Magnesium Hydroxide – Draws water into the intestines to facilitate comfortable elimination of waste material.*	Magnesium Hydroxide

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Laxative-3 Blend™	Slippery Herbal Blend – Supports healthy intestinal mucous.*	Magnesium Hydroxide, Proprietary Mucilage Blend: slippery elm (Ulmus rubra) bark, marshmallow (Althaea officinalis) root extract and fenugreek (Trigonella foenum-graecum) seed extract, Proprietary Soothing Blend: peppermint (Mentha x piperita) leaf, fennel (Foeniculum vulgare) seed and ginger (Zingiber officinale) rhizome extract

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Laxative-3 Blend™	Soothing Herbal Blend – Supports and soothes intestinal muscles.*	Magnesium Hydroxide, Proprietary Mucilage Blend: slippery elm (Ulmus rubra) bark, marshmallow (Althaea officinalis) root extract and fenugreek (Trigonella foenum-graecum) seed extract, Proprietary Soothing Blend: peppermint (Mentha x piperita) leaf, fennel (Foeniculum vulgare) seed and ginger (Zingiber officinale) rhizome extract

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