



ENZYMATIC THERAPY
INCORPORATED

*What **Better** feels like.™*

February 17, 2005

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>
Iberogast®	Relieves temporary bloating, stomach upset, gas and pressure*	Proprietary blend of the following herbal extracts: German chamomile (Matricaria recutita) flower, clown's mustard (Iberis amara) plant, angelica (Angelica archangelica) root and rhizome, caraway (Carum carvi) fruit, milk thistle (Silybum marianum) fruit, lemon balm (Melissa officinalis) leaf, celandine (Chelidonium majus) aerial part, licorice (Glycyrrhiza glabra) root, and peppermint (Mentha x piperita) leaf

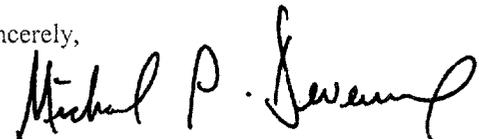
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/17/05

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

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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)

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Iberogast®	Quick relief for occasional nausea*	Proprietary blend of the following herbal extracts: German chamomile (<i>Matricaria recutita</i>) flower, clown's mustard (<i>Iberis amara</i>) plant, angelica (<i>Angelica archangelica</i>) root and rhizome, caraway (<i>Carum carvi</i>) fruit, milk thistle (<i>Silybum marianum</i>) fruit, lemon balm (<i>Melissa officinalis</i>) leaf, celandine (<i>Chelidonium majus</i>) aerial part, licorice (<i>Glycyrrhiza glabra</i>) root, and peppermint (<i>Mentha x piperita</i>) leaf

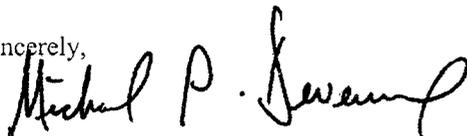
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Date: 2/17/05

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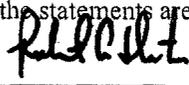
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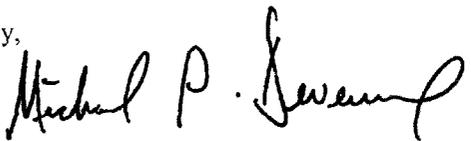
PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Iberogast®	Helps improve digestion*	Proprietary blend of the following herbal extracts: German chamomile (<i>Matricaria recutita</i>) flower, clown's mustard (<i>Iberis amara</i>) plant, angelica (<i>Angelica archangelica</i>) root and rhizome, caraway (<i>Carum carvi</i>) fruit, milk thistle (<i>Silybum marianum</i>) fruit, lemon balm (<i>Melissa officinalis</i>) leaf, celandine (<i>Chelidonium majus</i>) aerial part, licorice (<i>Glycyrrhiza glabra</i>) root, and peppermint (<i>Mentha x piperita</i>) leaf

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Iberogast®	Supports healthy muscular contraction and relaxation in the intestinal system.*	Proprietary blend of the following herbal extracts: German chamomile (<i>Matricaria recutita</i>) flower, clown's mustard (<i>Iberis amara</i>) plant, angelica (<i>Angelica archangelica</i>) root and rhizome, caraway (<i>Carum carvi</i>) fruit, milk thistle (<i>Silybum marianum</i>) fruit, lemon balm (<i>Melissa officinalis</i>) leaf, celandine (<i>Chelidonium majus</i>) aerial part, licorice (<i>Glycyrrhiza glabra</i>) root, and peppermint (<i>Mentha x piperita</i>) leaf

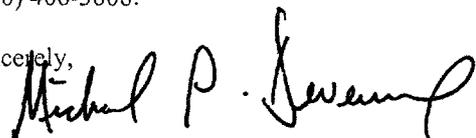
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