



**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)

December 1, 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

DEC -7 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.

<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
FlexAgility™ Max	Reduces pain and stiffness due to occasional overuse*	Proprietary Blend: Isooxygene, Ginger Root Extract, Boswellia Serrata, Rutin Flower Buds, Green Tea Leaf, Black Elderberry, Bromelain (2400 G.D.U. Pineapple Enzyme), Vitamin C (Ascorbic Acid), N-Acetylcysteine

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  
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/1/04

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

975 0162

LET 15248

FlexAgility Max

Also see docket 975-0163



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<b>PRODUCT NAME</b>	<b>STATEMENT</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
FlexAgility™ Max	Triple-Action relief helps you get active...get going!*	Proprietary Blend: Isooxygene, Ginger Root Extract, Boswellia Serrata, Rutin Flower Buds, Green Tea Leaf, Black Elderberry, Bromelain (2400 G.D.U. Pineapple Enzyme), Vitamin C (Ascorbic Acid), N-Acetylcysteine

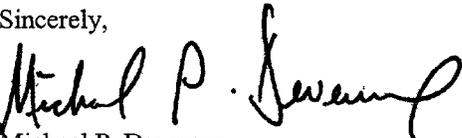
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Michael P. Devereux  
Chief Financial Officer



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December 2, 2004

Office of Nutritional Products, Labeling &  
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RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
FlexAgility™ Max	Clinically studied ingredients target occasional pain and stiffness due to overuse.*	Proprietary Blend: Isooxygene, Ginger Root Extract, Boswellia Serrata, Rutin Flower Buds, Green Tea Leaf, Black Elderberry, Bromelain (2400 G.D.U. Pineapple Enzyme), Vitamin C (Ascorbic Acid), N-Acetylcysteine

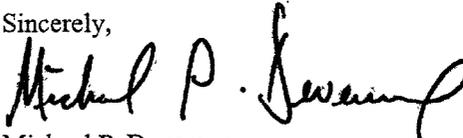
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By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/2/04

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PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
FlexAgility™ Max	The natural way to support healthy joints!*	Proprietary Blend: Isooxygene, Ginger Root Extract, Boswellia Serrata, Rutin Flower Buds, Green Tea Leaf, Black Elderberry, Bromelain (2400 G.D.U. Pineapple Enzyme), Vitamin C (Ascorbic Acid), N-Acetylcysteine

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Michael P. Devereux  
Chief Financial Officer



www.enzymatic.com

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<b>PRODUCT NAME</b>	<b>STATEMENT</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
FlexAgility™ Max	Enzyme support for healthy joint function*	Proprietary Blend: Isooxygene, Ginger Root Extract, Boswellia Serrata, Rutin Flower Buds, Green Tea Leaf, Black Elderberry, Bromelain (2400 G.D.U. Pineapple Enzyme), Vitamin C (Ascorbic Acid), N-Acetylcysteine

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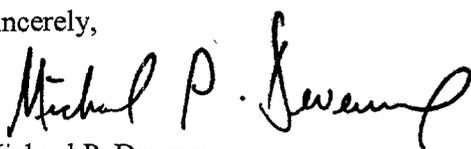
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