



**ENZYMATIC THERAPY**  
INCORPORATED

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March 8, 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

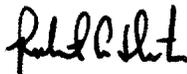
RE: Label Claims/Disclaimers

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.

PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
FlexAgility™* Max	Antioxidants play an important role in the prevention and elimination of free radicals and reactive oxygen species (ROS).*	Vitamin C (Ascorbic Acid), Proprietary Flex Blend: hops (Humulus lupulus) (IsoOxygene™ brand) flower extract, ginger (Zingiber officinale) rhizome extract, Boswellia serrata gum extract, Bromelain, Japanese Sophora (Sophora japonica) Flower Bud, European Elder (Sambucus nigra) Berry Extract, Green Tea (Camellia sinensis) Leaf Extract, N-Acetylcysteine (NAC)

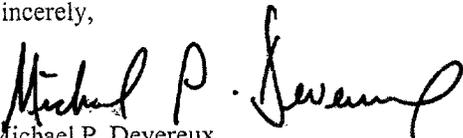
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 3/8/05

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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# ENZYMATIC THERAPY INCORPORATED

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## INTEGRATIVE THERAPEUTICS INC.™

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## 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)

March 8, 2005

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PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
FlexAgility™* Max	When free radicals and ROS react with our cells, the inflammatory cascade is initiated.* Clinical studies have shown that antioxidant supplementation can reduce the pain and stiffness associated with occasional overuse.* Through the neutralization of free radicals and ROS, antioxidants play an important role in maintaining optimum health.*	Vitamin C (Ascorbic Acid), Proprietary Flex Blend: hops (Humulus lupulus) (IsoOxygene™ brand) flower extract, ginger (Zingiber officinale) rhizome extract, Boswellia serrata gum extract, Bromelain, Japanese Sophora (Sophora japonica) Flower Bud, European Elder (Sambucus nigra) Berry Extract, Green Tea (Camellia sinensis) Leaf Extract, N-Acetylcysteine (NAC)

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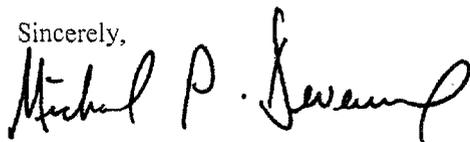
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/8/05

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Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Devereux". The signature is fluid and cursive, with a large initial "M" and a distinct "P" and "D".

Michael P. Devereux  
Chief Financial Officer



**ENZYMATIC THERAPY**  
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March 9, 2005

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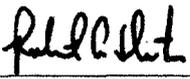
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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
FlexAgility™* Max	Vitamin C is a well-known antioxidant and powerful free radical scavenger. Research has shown that supplemental vitamin C prevents oxidative damage. In addition, studies confirm that treatment with vitamin C supports the production of healthy collagen.*	Vitamin C (Ascorbic Acid), Proprietary Flex Blend: hops ( <i>Humulus lupulus</i> ) (IsoOxygene™ brand) flower extract, ginger ( <i>Zingiber officinale</i> ) rhizome extract, Boswellia serrata gum extract, Bromelain, Japanese Sophora ( <i>Sophora japonica</i> ) Flower Bud, European Elder ( <i>Sambucus nigra</i> ) Berry Extract, Green Tea ( <i>Camellia sinensis</i> ) Leaf Extract, N-Acetylcysteine (NAC)

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Date: 3/9/05

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Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is written in a cursive style with a large, prominent "M" and "D".

Michael P. Devereux  
Chief Financial Officer



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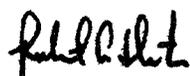
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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
FlexAgility™* Max	Traditionally used for bladder health and immune system support, elder berry is also known for its significant antioxidant properties.*	European Elder (Sambucus nigra) Berry Extract

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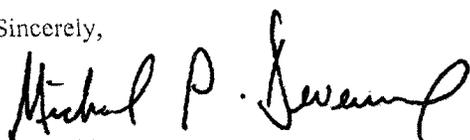
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Title: Senior Vice President of Scientific Affairs

Date: 3/10/05

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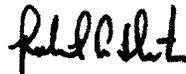
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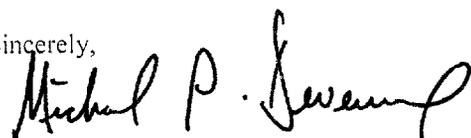
<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
FlexAgility™* Max	Elder berry continues to gain recognition for its ability to support the body's natural anti-inflammatory response.*	European Elder (Sambucus nigra) Berry Extract

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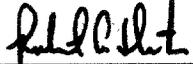
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FlexAgility™* Max	Bioflavonoids play a major role in reducing free radical damage through synthesis and cross-linking of collagen.* Rutin is a well-known, potent bioflavonoid. A comparative study of flavonoids found that rutin effectively reduces pain and stiffness due to occasional overuse.*	Japanese Sophora (Sophora japonica) Flower Bud standardized to contain 95% rutin

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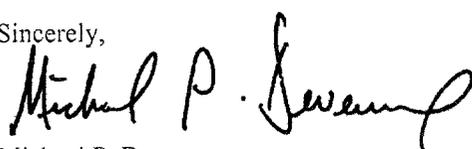
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Michael P. Devereux  
Chief Financial Officer

FlexAgility Max 33e



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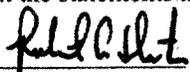
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FlexAgility™* Max	Boswellic acids, the key component of Boswellia serrata, have been shown to reduce pain associated with occasional overuse.* The herb blocks synthesis of inflammatory mediators, such as leukotrienes, which are known to promote free radical damage.* As with green tea, ginger, and elder berry, long term use of boswellia has been shown to be safe and effective.*	Ginger (Zingiber officinale), European Elder (Sambucus nigra) Berry Extract, Boswellia serrata gum extract, Green Tea (Camellia sinensis) Leaf Extract

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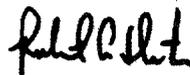
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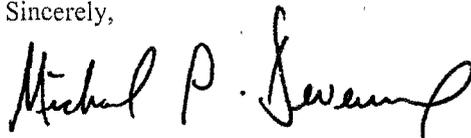
<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
FlexAgility™* Max	Significantly inhibits COX-2 with minimal affect on COX-1 levels.*	Hops (Humulus lupulus) (IsoOxygene™ brand) Flower Extract

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Robert C. Doster  
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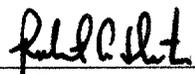
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FlexAgility™* Max	Reduces prostaglandin and increases blood flow, supporting the body's natural anti-inflammatory function.*	Bromelain

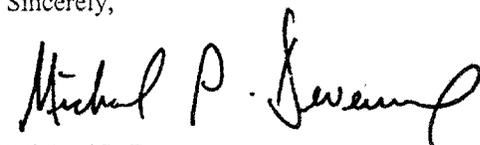
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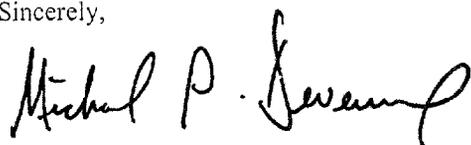
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