



ENZYMATIC THERAPY
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What **Better** feels like.™

February 21, 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	Its clinically studied ingredients have been shown to help balance the body's natural anti-inflammatory response through three separate mechanisms.*	Vitamin C (Ascorbic Acid), Proprietary Flex Blend: hops (<i>Humulus lupulus</i>) (IsoOxygene™ brand) flower extract, ginger (<i>Zingiber officinale</i>) rhizome extract, <i>Boswellia serrata</i> , 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)

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: 2/21/05

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®
&
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)

FEB 25 2005



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NF Formulas ♦ PhytoPharmica
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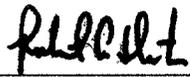
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PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
FlexAgility™* Max	Patented IsoOxygene™ safely and significantly inhibits cyclooxygenase enzyme-2, an important biochemical regulator of inflammation.*	Vitamin C (Ascorbic Acid), Proprietary Flex Blend: hops (<i>Humulus lupulus</i>) (IsoOxygene™ brand) flower extract, ginger (<i>Zingiber officinale</i>) rhizome extract, <i>Boswellia serrata</i> , 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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Robert C. Doster
Title: Senior Vice President of Scientific Affairs

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Chief Financial Officer



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PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
FlexAgility™* Max	FlexAgility MAX also includes powerful free radical scavengers, and the enzyme bromelain, which have unique activity in blocking compounds that cause inflammation.*	Vitamin C (Ascorbic Acid), Proprietary Flex Blend: hops (<i>Humulus lupulus</i>) (<i>IsoOxygene™</i> brand) flower extract, ginger (<i>Zingiber officinale</i>) rhizome extract, <i>Boswellia serrata</i> , 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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February 22, 2005

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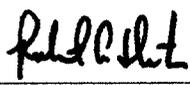
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PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
FlexAgility™* Max	FlexAgility MAX supports the body's natural anti-inflammatory function during times of occasional overuse.*	Vitamin C (Ascorbic Acid), Proprietary Flex Blend: hops (<i>Humulus 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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PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
FlexAgility™* Max	Studies have shown that the alpha acids, humulone, isohumulone, and cohumulone, present in hops inhibit this enzyme.*	Hops (<i>Humulus lupulus</i>) (IsoOxygene™ brand) flower 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.

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PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
FlexAgility™* Max	IsoOxygene™ is a patented hops extract specifically designed to inhibit the COX-2 enzyme without affecting COX-1.*	Hops (<i>Humulus lupulus</i>) (IsoOxygene™ brand) flower extract

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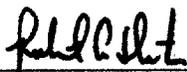
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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
FlexAgility™ Max	IsoOxygene is also far more selective than botanicals and drugs designed to reduce pain due to occasional overuse.* IsoOxygene can therefore be used safely without adversely affecting the homeostatic functions regulated by COX-1.*	Hops (<i>Humulus lupulus</i>) (IsoOxygene™ brand) flower extract

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