

Enzymatic Therapy

NATURAL MEDICINES®

9 12 0 03 170-1 71 89

October 13, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RECEIVED
NOV 05 2003
BY:

RE: Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility™*	Proprietary Herbal Extract Blend ginger (Zingiber officinale) rhizome extract and greater galangal (Alpinia galanga) rhizome extract	FlexAgility™* contains EV.EXT® 77, a proprietary blend of ginger (Zingiber officinale) and greater galanga (Alpinia galanga) that has been clinically studied to support joint health.*

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

Title: Senior Vice President Scientific Affairs

Date: 10/13/03

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
FlexAgility 7c

825 Challenger Drive
Green Bay, WI 54311-8328
Ph: 920-469-1313
Fax: 888-570-6460
www.enzy.com

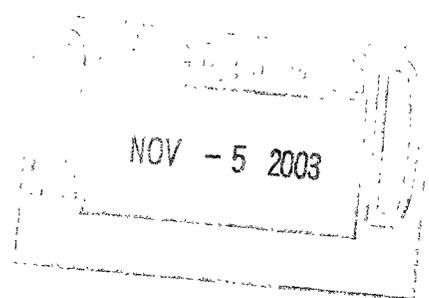
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Enzymatic Therapy

NATURAL MEDICINES®

October 14, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



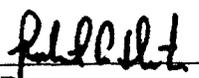
RE: Label Claims/Disclaimers

Dear Mr. Moore:

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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility™*	Proprietary Herbal Extract Blend ginger (Zingiber officinale) rhizome extract and greater galangal (Alpinia galanga) rhizome extract	FlexAgility™* supports healthy musculoskeletal, cartilage, and joint function.*

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.

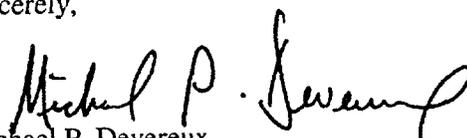
By: 
Robert Doster

Title: Senior Vice President Scientific Affairs

Date: 10/14/03

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
FlexAgility &c

Enzymatic Therapy

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October 14, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
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5100 Paint Branch Parkway
College Park, MD 20740

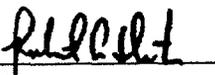
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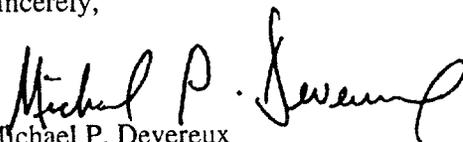
<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility™*	Proprietary Herbal Extract Blend ginger (Zingiber officinale) rhizome extract and greater galangal (Alpinia galanga) rhizome extract	Ginger and ginger extracts are known to reduce stiffness due to occasional overuse.*

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
Title: Senior Vice President Scientific Affairs
Date: 10/14/03

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
FlexAgility 9e

Enzymatic Therapy

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October 14, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
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5100 Paint Branch Parkway
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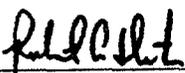
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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility™*	Proprietary Herbal Extract Blend ginger (Zingiber officinale) rhizome extract and greater galangal (Alpinia galanga) rhizome extract	Certain compounds in ginger are believed to be responsible for inhibition of biochemical mediation.*

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: 

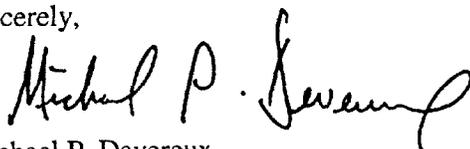
Robert Doster

Title: Senior Vice President Scientific Affairs

Date: 10/14/03

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

FlexAgility 10e

825 Challenger Drive
Green Bay, WI 54311-9328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Enzymatic Therapy

NATURAL MEDICINES®

October 15, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

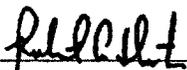
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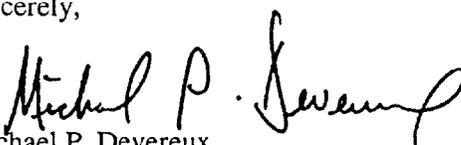
<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility™*	Proprietary Herbal Extract Blend ginger (Zingiber officinale) rhizome extract and greater galangal (Alpinia galanga) rhizome extract	Hydroxy-alkoxy-phenyl ginger compounds inhibit the production of cytokines known to affect cartilage.*

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
Title: Senior Vice President Scientific Affairs
Date: 10/15/03

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
FlexAgility 11e

Enzymatic Therapy

NATURAL MEDICINES®

October 15, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility™*	Proprietary Herbal Extract Blend ginger (Zingiber officinale) rhizome extract and greater galangal (Alpinia galanga) rhizome extract	Gingerols and shogaols, Zingiber officinale components, have several beneficial biochemical activities. Both inhibit arachidonic acid metabolism, resulting in suppression of prostaglandin and leukotriene synthesis from arachidonic acid via the cyclooxygenase and lipoxygenase pathways.*

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

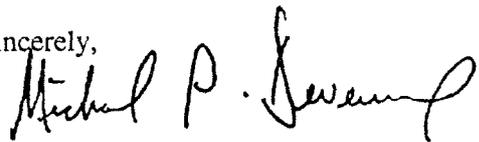
Robert Doster

Title: Senior Vice President Scientific Affairs

Date: 10/15/03

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, prominent initial "M".

Michael P. Devereux
Chief Financial Officer

Enzymatic Therapy

NATURAL MEDICINES®

October 15, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility™*	Proprietary Herbal Extract Blend ginger (Zingiber officinale) rhizome extract and greater galangal (Alpinia galanga) rhizome extract	In a case report, individuals took either 5 grams of fresh ginger, 50 grams of fresh ginger, or 0.5 to 1.0 grams of powdered ginger for a period of 30 days. All individuals reported support of joint health.* A larger study examined the effect of taking ginger extracts for periods of time ranging from 3 months to 2.5 years. All 56 individuals taking the ginger extracts reported support of joint health.*

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 Scientific Affairs

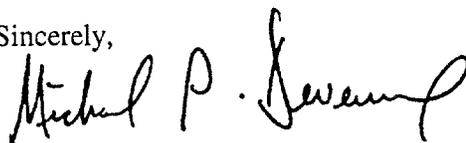
Date: 10/15/03

825 Challenger Drive
Green Bay, WI 54311-8328
Ph: 920-469-1313
Fax: 888-570-6460
www.enzy.com

FlexAgility 13c

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux
Chief Financial Officer

Enzymatic Therapy

NATURAL MEDICINES®

October 17, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

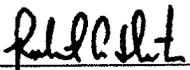
RE: Label Claims/Disclaimers

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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility™*	Proprietary Herbal Extract Blend ginger (Zingiber officinale) rhizome extract and greater galangal (Alpinia galanga) rhizome extract	Several studies have examined the possible mechanisms of action associated with Alpinia galanga. Antioxidative properties have been identified in galangal extracts.*

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.

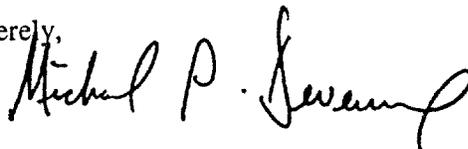
By: 
Robert Doster

Title: Senior Vice President Scientific Affairs

Date: 10/17/03

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
FlexAgility 15c

Enzymatic Therapy

NATURAL MEDICINES®

October 18, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

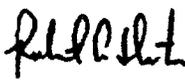
RE: Label Claims/Disclaimers

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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility™*	Proprietary Herbal Extract Blend ginger (Zingiber officinale) rhizome extract and greater galangal (Alpinia galanga) rhizome extract	One of galangal's key compounds is acetoxychavicol acetate. Research has demonstrated that this compound effectively inhibits NO production.* Additionally, acetoxychavicol acetate inhibits phagocytosis and activates protein kinase C.

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: 

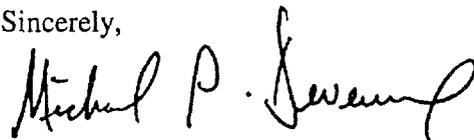
Robert Doster

Title: Senior Vice President Scientific Affairs

Date: 10/18/03

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux
Chief Financial Officer

Enzymatic Therapy

NATURAL MEDICINES®

October 19, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

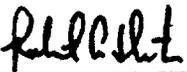
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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility™*	Proprietary Herbal Extract Blend ginger (Zingiber officinale) rhizome extract and greater galangal (Alpinia galanga) rhizome extract	FlexAgility™* inhibits mainly the COX-2 enzyme, with only mild inhibition of the protective COX-1 prostaglandins.*

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

Title: Senior Vice President Scientific Affairs

Date: 10/19/03

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
FlexAgility 19e

Enzymatic Therapy

NATURAL MEDICINES®

October 21, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

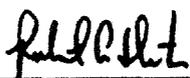
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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility™*	Proprietary Herbal Extract Blend ginger (Zingiber officinale) rhizome extract and greater galangal (Alpinia galanga) rhizome extract	FlexAgility™* is rapidly absorbed and maintained in the blood for extended periods of time.*

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.

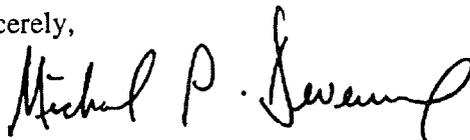
By: 
Robert Doster

Title: Senior Vice President Scientific Affairs

Date: 10/21/03

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
FlexAgility 20e

Enzymatic Therapy

NATURAL MEDICINES®

October 21, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

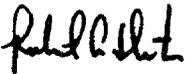
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Enzymatic Therapy, Inc.	FlexAgility™*	Proprietary Herbal Extract Blend ginger (Zingiber officinale) rhizome extract and greater galangal (Alpinia galanga) rhizome extract	Pharmacokinetic studies indicate that the patented extraction form is responsible for FlexAgility™* superior effectiveness.*

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

Title: Senior Vice President Scientific Affairs

Date: 10/21/03

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

FlexAgility 21e