



JAN 14 2005

Mr. Michael P. Devereux
Chief Financial Officer
Enzymatic Therapy, Inc.
825 Challenger Drive
Green Bay, Wisconsin 54311

Dear Mr. Devereux:

This is in response to your letter of December 28, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Enzymatic Therapy, Inc. is making the following claims, among others, for the product **FlexAgility™ Max**:

“Reduces Pain”

“Supports your body’s own anti-inflammatory response.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to prevent or treat disease because they imply that the product is intended to treat arthritis. Arthritis is defined as “Inflammation of a joint or a state characterized by inflammation of joints.” Stedman’s Medical Dictionary, 26th Edition. The claims for the product unambiguously describe its intended use for “relief” of joint pain from inflammatory joint conditions. Taken together, these claims evidence that the product is intended for use in the diagnosis, mitigation, treatment, cure, or prevention of a specific disease, namely, arthritis. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

975-0163

LET 805

Page 2 - Mr. Michael P. Devereux

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal flourish extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-CE840



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Tyler Encapsulations ◀ Vitaline Formulas
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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 28, 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

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	Maximum Relief*	Proprietary Blend: Isooxygene, Ginger Root Extract, Boswellia Serrata, Rutin Flower Buds, Green Tea Leaf, Black Elderberry, Bromelain, 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

Title: Senior Vice President of Scientific Affairs

Date: 12-28-04

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

90573



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December 28, 2004

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Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

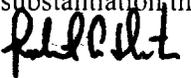
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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
FlexAgility™* Max	The safe, natural way to support healthy joints!*	Proprietary Blend: Isooxygene, Ginger Root Extract, Boswellia Serrata, Rutin Flower Buds, Green Tea Leaf, Black Elderberry, 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

Title: Senior Vice President of Scientific Affairs

Date: 12-28-04

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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December 29, 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

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	Supports your body's own anti-inflammatory response.*	Proprietary Blend: Isooxygene, Ginger Root Extract, Boswellia Serrata, Rutin Flower Buds, Green Tea Leaf, Black Elderberry, Bromelain, 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: 12-29-04

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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December 20, 2004

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
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5100 Paint Branch Parkway
College Park, MD 20740

*Rec'd
12/23/04*

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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
FlexAgility™* Max	-Reduces Pain -Relieves 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: *12/20/04*

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Sincerely,

Michael P. Devereux
Michael P. Devereux
Chief Financial Officer