



DEC 29 2004

Mr. Michael P. Devereux  
Chief Financial Officer  
Enzymatic Therapy  
825 Challenger Drive  
Green Bay, Wisconsin 54311-8328

Dear Mr. Devereux:

This is in response to your letter of December 1, 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 claims identified below for the product **FlexAgility™ Max**.

The product **FlexAgility™ Max** uses the claims "Reduces pain...due to occasional overuse" and "Clinically studies ingredients target occasional pain...due to overuse." These claims are disease claims because they suggests that the product is intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis, when considered in the context of the other claims regarding the promotion of joint health and joint protection. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1016-17), FDA stated that "joint pain" is characteristic of arthritis and that it is the most sensitive physical sign of rheumatoid arthritis. For that reason, the agency concluded that claims about relieving joint pain are implied disease claims because they represent that the product will have an affect on a characteristic sign or symptom of a disease (see 21 CFR 101.93(g)(2)(ii)). Moreover, elsewhere in the preamble to the final rule (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. We stated that since pain is not a normal state, nor are there "normal pain levels," a claim about pain treatment or prevention is ordinarily a disease claim. We addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. We added, however, that a acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise.

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Page 2 - Mr. Michael P. Devereux

The claims contained in your notification do not refer to pain associated with a non-disease state. Although "occasional overuse" is not itself a disease, such an activity would not be expected to result in joint pain unless a person already suffered from an underlying disease that predisposed him or her to such pain.

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

*for* 

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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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

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  
Vice President of 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

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: 12/2/04

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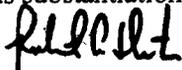
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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
FlexAgility™ Max	The natural way to support healthy joints!*	Proprietary Blend: Isooxygene, Ginger Root Extract, Boswellia Serrata, Rutin Flower Buds, Green Tea Leaf,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

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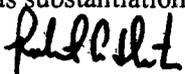
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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
FlexAgility™ Max	Enzyme support for healthy joint function*	Proprietary Blend: Isooxygene, Ginger Root Extract, Boswellia Serrata, Rutin Flower Buds, Green Tea Leaf,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

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FlexAgility™ Max	Joint-specific antioxidant protection*	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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