

# Enzymatic Therapy

NATURAL MEDICINES®

January 21, 2004

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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>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pure Agility™*	Dietary Supplement for increased support of joints and prolonged flexibility*	Chloride (from glucosamine sulfate), Sodium, Glucosamine Sulfate, Chondroitin Sulfate (from marine source)

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: 1/21/04

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

Pure Agility 1c

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pure Agility™*	Pure Agility™* combines glucosamine sulfate with low molecular weight, marine-source chondroitin sulfate. The result is a highly absorbable formula offering ultimate support for joints and cartilage.*	Glucosamine Sulfate, Chondroitin Sulfate (from marine source)

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

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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/21/04

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Michael P. Devereux  
Chief Financial Officer

Pure Agility 2c

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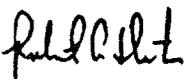
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pure Agility™*	Our chondroitin sulfate has an average molecular weight less than 16,000 daltons-less than half the molecular weight of most chondroitin products. This results in improved absorption.*	Chondroitin Sulfate (from marine source)

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By: 

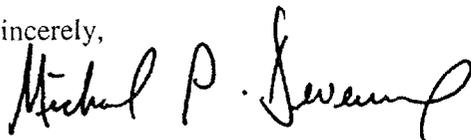
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Title: Senior Vice President of Scientific Affairs

Date: 1/22/04

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Michael P. Devereux  
Chief Financial Officer

Pure Agility 3e

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

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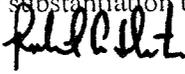
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pure Agility™*	Glucosamine is a basic building block of cartilage and is required for the lubrication of joints.*	Glucosamine Sulfate

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pure Agility™*	The chondroitin sulfate in Pure Agility is low molecular weight, which aids in its absorption into joint cartilage.*	Chloride (from glucosamine sulfate), Sodium, Glucosamine Sulfate, Chondroitin Sulfate (from marine source)

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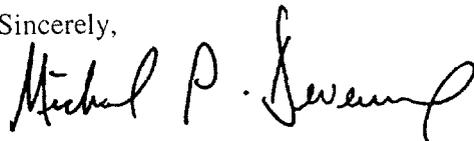
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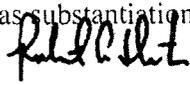
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Pure Agility™*	Pure Agility ensures that those beneficial compounds reach joints at full potency.*	Chloride (from glucosamine sulfate), Sodium, Glucosamine Sulfate, Chondroitin Sulfate (from marine source)

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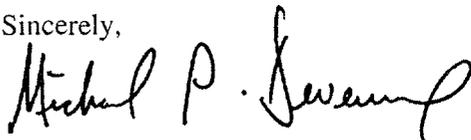
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