



**ENZYMATIC THERAPY**

INCORPORATED

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**INTEGRATIVE THERAPEUTICS INC.™**

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9755 SW Commerce Circle, Suite B2  
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)

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October 18, 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

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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	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cherry Fruit Extract	Anthocyanins flavonoids isolated from cherries have been shown to possess antioxidant capabilities superior to vitamin E.* This powerful free radical scavenging capacity has broad ranging health implications for the immune, cardiovascular, and musculoskeletal systems.* Additionally, cherries have also been shown to support the body's natural anti-inflammatory response.*	Sweet Cherry (Prunus avium) Fruit 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.

By: Robert Doster  
Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 10/18/05

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

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cherry Fruit Extract	One of the most exciting new findings regarding cherry fruit consumption is its potential support in the area of cardiovascular health.*	Sweet Cherry ( <i>Prunus avium</i> ) Fruit Extract

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Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 10/18/05

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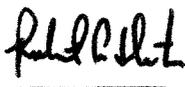
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cherry Fruit Extract	Cherry consumption may help maintain healthy insulin and blood sugar levels that are already within the normal range.*	Sweet Cherry ( <i>Prunus avium</i> ) Fruit Extract

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By: 

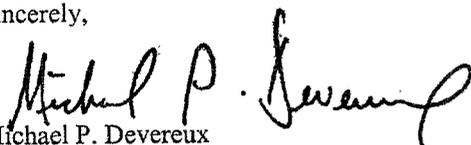
Robert Doster

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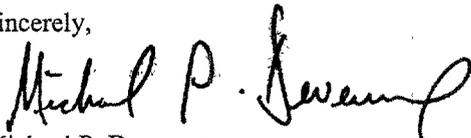
PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cherry Fruit Extract	A recent study, the first to reveal that melatonin can be naturally present in food sources, found that both sweet and tart cherries contain high levels of melatonin. While additional trials are needed to validate cherry fruit as an effective sleep enhancer, this study implies yet another potential health benefit of cherry consumption.*	Sweet Cherry ( <i>Prunus avium</i> ) Fruit Extract

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