

## ENZYMATIC THERAPY

INCORPORATED

What Better feels like."

July 27, 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

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
Recancostat®	Supports healthy cell apoptosis*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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 of Scientific Affairs

nlanlos Date:

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

Sincerely,

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Michael P. Devereux Chief Financial Officer

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INTEGRATIVE THERAPEUTICS INC." NF Formulas \* PhytoPharmica Tyler Encapsulations \* Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 🤞

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 👒 F: 888.570.6460 (Enzymatic) P2:16



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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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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	Manages healthy cell apoptosis*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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.

Robert Doster Title: Senior Vice President of Scientific Affairs

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Michael P. Devereux Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	Supports the body's normal process of DNA repair.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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

7/28/05 Date:

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Michael P. Devereux Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	GSH blocks free-radical damage to all types of tissue and supports the body's normal process of DNA repair.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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