



ENZYMATIC THERAPY
INCORPORATED

What **Better** feels like™

INTEGRATIVE THERAPEUTICS INC.™

NF Formulas ◊ PhytoPharmica
◊ Tyler Encapsulations ◊ Vitaline Formulas

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)

October 19, 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.

| PRODUCT NAME | STATEMENTS | INGREDIENTS TO WHICH THE CLAIMS RELATE |
|--------------|--|---|
| Recancostat® | Recancostat is a patented combination of reduced glutathione (GSH), anthocyanins, and l-cysteine. This oral supplement has been clinically studied for support of healthy cell development.* | L-Glutathione, Reduced, AnthroRedoxin™ (min 10% anthocyanins): Beet Root (Beta vulgaris), Bilberry Berry Extract (Vaccinium myrtillus), Black Currant Berry (Ribes nigrum), European Elder Berry Extract (Sambucus nigra), 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 C. Doster
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date 10/19/04

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
Chief Financial Officer

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OCT 29 2004



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| | | |
|--------------|---|------------------------|
| | | |
| Recancostat® | The key ingredient in Recancostat is GSH. Reduced GSH is naturally occurring in the body and is present in every type of cell. It is essential to cellular detoxification, amino acid transport, production of coenzymes and recycling of vitamins E and C.* A powerful antioxidant that functions inside the cells, reduced glutathione blocks free radical damage to all types of tissues.* | L-Glutathione, Reduced |

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.

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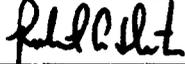
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| PRODUCT NAME | STATEMENTS | INGREDIENTS |
|--------------|---|---|
| Recancostat® | Recancostat combines the essential tripeptide glutathione (GSH or reduced glutathione) and the important amino acid L-cysteine with a group of potent antioxidants called anthocyanins.* Adequate levels of GSH and antioxidants are desirable for supporting immune function.* | L-Glutathione, Reduced, AnthroRedoxin™ (min 10% anthocyanins): Beet Root (Beta vulgaris), Bilberry Berry Extract (Vaccinium myrtillus), Black Currant Berry (Ribes nigrum), European Elder Berry Extract (Sambucus nigra), L-Cysteine |

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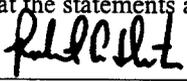
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| PRODUCT NAME | STATE | SUBSISTING DOCUMENTS |
|--------------|-------|--|
| Recancostat® | | Supplementation, including the use of convenient oral administration has been shown to increase both circulating and tissue concentrations of this important nutrient.* L-Glutathione, Reduced, AnthroRedoxin™ (min 10% anthocyanins): Beet Root (Beta vulgaris), Bilberry Berry Extract (Vaccinium myrtillus), Black Currant Berry (Ribes nigrum), European Elder Berry Extract (Sambucus nigra), L-Cysteine |

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