



**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)

August 13, 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

AUG 13 2004

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
Restore Formula	Supports the body's natural anti-inflammatory function.*	Hops Extract, Boswellia Root Extract, Haematococcus Algae, Milk Thistle Seed Extract, Vitamin E, Selenium

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: 8/13/04

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

97S 0162 LET 14517



**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)

August 13, 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

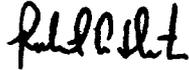
RE: Label Claims/Disclaimers

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>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Restore Formula	Helps balance the body's natural inflammatory response.*	Hops Extract, Boswellia Root Extract, Haematococcus Algae, Milk Thistle Seed Extract, Vitamin E, Selenium

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: 8/13/04

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



**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)

August 13, 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

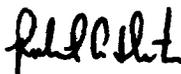
RE: Label Claims/Disclaimers

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.

<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Restore Formula	Supports the body's natural anti-inflammatory response by inhibiting the enzymatic activity of cyclooxygenase & lipoxygenase and by reducing the production of C-Reactive Protein.*	Hops Extract, Boswellia Root Extract, Haematococcus Algae, Milk Thistle Seed Extract, Vitamin E, Selenium

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: 8/13/04

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



**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)

August 14, 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>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Restore Formula	Naturally supports the body's own anti-inflammatory responses.*	Hops Extract, Boswellia Root Extract, Haematococcus Algae, Milk Thistle Seed Extract, Vitamin E, Selenium

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: 8/14/04

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



**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)

August 14, 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	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Restore Formula	Support for healthy C-RP levels.*	Hops Extract, Boswellia Root Extract, Haematococcus Algae, Milk Thistle Seed Extract, Vitamin E, Selenium

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: 8/14/04

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



**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)

August 14, 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>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Restore Formula	Reduces C-Reactive Protein.*	Hops Extract, Boswellia Root Extract, Haematococcus Algae, Milk Thistle Seed Extract, Vitamin E, Selenium

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: 8/14/04

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



**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)

August 15, 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.

<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Restore Formula	Studies show that Vitamin E can reduce the amount of C-RP in the blood.*	Vitamin E

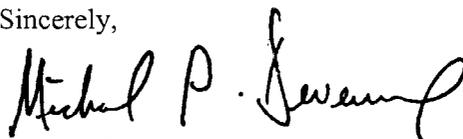
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 8/15/04

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



**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)

August 15, 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

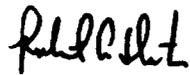
RE: Label Claims/Disclaimers

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>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Restore Formula	Low C-RP levels have been associated with healthy heart (or other appropriate system) function.*	Hops Extract, Boswellia Root Extract, Haematococcus Algae, Milk Thistle Seed Extract, Vitamin E, Selenium

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: 8/15/04

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



**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)

August 15, 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>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Restore Formula	Reduces inflammation associated with occasional overuse.*	Hops Extract, Boswellia Root Extract, Haematococcus Algae, Milk Thistle Seed Extract, Vitamin E, Selenium

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: 

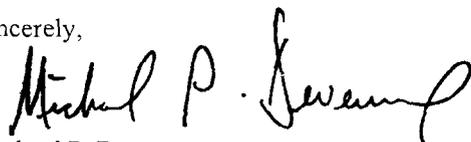
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 8/15/04

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