



INTEGRATIVE THERAPEUTICS INC.™
 NF Formulas ◊ PhytoPharmica
 Tyler Encapsulations ◊ Vitaline Formulas

ENZYMATIC THERAPY™
 &
PHYTOPHARMICA™

ENZYMATIC THERAPY
 INCORPORATED

*What **Better** feels like.™*

9755 SW Commerce Circle, Suite B2
 Wilsonville, OR 97070
 P: 503.582.8386 ◊ F: 503.582.0467

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)

0499 6 JAN 12 P2:38

January 3, 2006

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

JAN 5 2006

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>
Menopause Transition* with Black Cohosh	Provides relief of hot flashes, night sweats and irritability*	Black Cohosh (Cimicifuga racemosa) Root and Rhizome 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.

Robert Doster

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

Date: 1-3-06

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

Sincerely,

 Michael P. Devereux
 Chief Operations Officer

975 0162 LET 17162



ENZYMATIC THERAPY

What **Better** feels like.™

What **Better** feels like.™

January 3, 2006

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>
Menopause Transition* with Black Cohosh	Black cohosh is the most widely used and thoroughly studied natural supplement for menopause relief.*	Black Cohosh (Cimicifuga racemosa) Root and Rhizome 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: 1-3-06

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 Operations Officer

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)



ENZYMATIC THERAPY

What **Better** feels like.™

January 3, 2006

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>
Menopause Transition* with Black Cohosh	Black Cohosh provides safe and natural hormonal support and relief of occasional hot flashes, irritability, and mood swings.*	Black Cohosh (Cimicifuga racemosa) Root and Rhizome 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

Title: Senior Vice President of Scientific Affairs

Date: _____

1-3-06

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

Sincerely,

Michael P. Devereux
Chief Operations Officer

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)



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)

ENZYMATIC THERAPY

What Better feels like.™

January 3, 2006

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

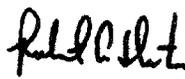
RE: Label Claims/Disclaimers

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.

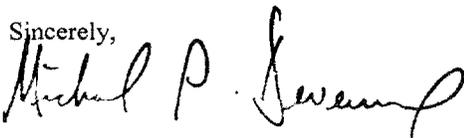
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Menopause Transition* with Black Cohosh	Black cohosh helps offset hormonal fluctuations that can result in occasional night sweats.*	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract

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
 Title: Senior Vice President of Scientific Affairs

Date: 1-3-06

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

Sincerely,

 Michael P. Devereux
 Chief Operations Officer



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)

ENZYMATIC THERAPY

What Better feels like.™

January 3, 2006

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

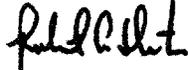
RE: Label Claims/Disclaimers

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>
Menopause Transition* with Black Cohosh	A randomized, placebo-controlled, double-blind study compared women who took standardized black cohosh extract with women taking conjugated estrogen or a placebo. At the end of the study, the women taking the standardized black cohosh extract showed improvement relative to the placebo as measured by the Kupperman Menopausal Index, the Hamilton Anxiety Scale, and the maturation index of vaginal epithelium.* No clear improvement of menopausal complaints was observed in the control group. This study demonstrated clinical and statistical improvement of symptoms by the women taking the standardized black cohosh extract.*	Black Cohosh (Cimicifuga racemosa) Root and Rhizome 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
 Title: Senior Vice President of Scientific Affairs

Date: 1-3-06

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

Sincerely,

 Michael P. Devereux
 Chief Operations Officer



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)

ENZYMATIC THERAPY

*What **Better** feels like.™*

January 3, 2006

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>
Menopause Transition* with Black Cohosh	Because of the effectiveness of relieving menopausal symptoms, black cohosh was originally believed to have a hormonal-like action.* Though the exact mechanism of action has not been clearly defined, recent studies have found black cohosh to have no estrogenic activity. It is now theorized that the action of black cohosh is a more central, dopaminergic like action. This theory postulates a link between serotonin receptors and the hypothalamus.	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract

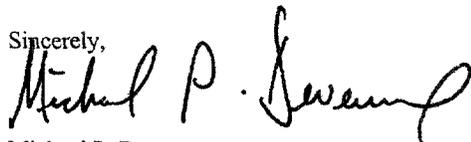
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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

Date: 1-3-06

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

Sincerely,



Michael P. Devereux
Chief Operations Officer