



**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

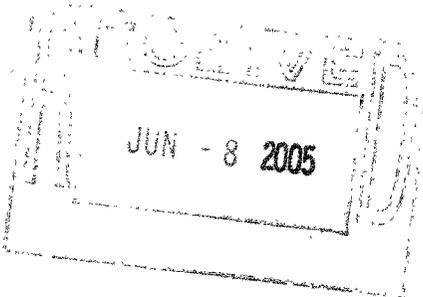
**ENZYMATIC THERAPY™**  
&  
**PHYTOPHARMICA™**

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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May 19, 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
Remifemin®	The effectiveness of Remifemin in the management of menopausal symptoms has been established from rigorous, well-controlled, clinical trials as well as open clinical monitoring trials in physician's practices studying over 1200 women in total.*	Black Cohosh

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 5-19-05

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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16272



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	A total of 304 women were randomly allocated to receive 40mg of Remifemin or matching placebo daily for 12 weeks. The results showed that women in the Remifemin group experienced a significant decrease in hot flashes.* No significant adverse effects were reported.*	Black Cohosh

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 5/19/05

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May 20, 2005

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	Clinical Studies of Remifemin conclude that statistically significant improvement in all scales especially in early menopause.*	Black Cohosh

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 5-20-05

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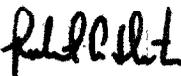
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	Clinical Studies of Remifemin conclude that statistically significant improvement in all scales of menopausal symptoms.*	Black Cohosh

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By: 

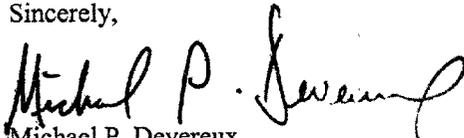
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Title: Senior Vice President of Scientific Affairs

Date 5-20-05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	Clinical Studies of Remifemin conclude that statistically significant improvement in all daily and weekly hot flashes.*	Black Cohosh

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

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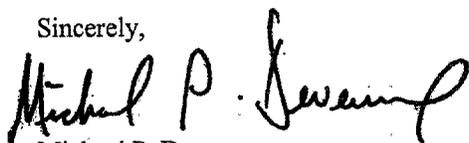
PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	A clinical study of Remifemin found an 80% improvement of menopausal symptoms.*	Black Cohosh

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  
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Date 5/20/05

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May 25, 2005

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	A recent double-blind study confirms the significant reduction of menopausal symptoms, particularly in women in early stages of menopause, with no adverse side-effects.*	Black Cohosh

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By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date 5/25/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	Effective – Recent clinical study shows a 70% reduction in hot flashes, night sweats, mood swings, irritability and related occasional sleeplessness.*	Black Cohosh

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