



**ENZYMATIC THERAPY**  
INCORPORATED

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**INTEGRATIVE THERAPEUTICS INC.™**

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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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January 5, 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

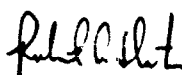
RE: Label Claims/Disclaimers

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.

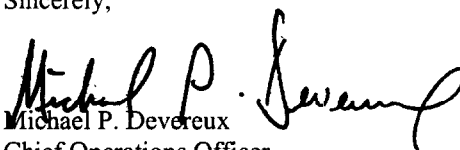
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	Improves night time sleep*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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 C. Doster  
Title: Senior Vice President of Scientific Affairs  
Date: 1/5/06

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

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	Helps ensure a sound night's sleep.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster  
Robert C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 1/5/06

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Sincerely,

Michael P. Devereux  
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Chief Operations Officer



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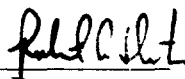
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	Fall asleep naturally, stay asleep, and wake up refreshed.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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Title: Senior Vice President of Scientific Affairs

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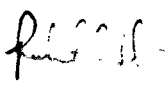
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	No morning grogginess*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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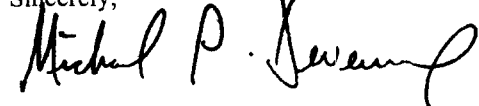
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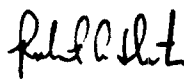
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	Wake up refreshed, not groggy*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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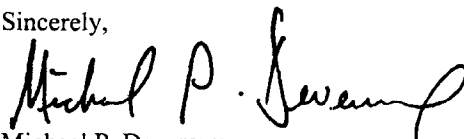
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Title: Senior Vice President of Scientific Affairs

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	For deep, sleep-filled nights and refreshing mornings with no groggy side effects.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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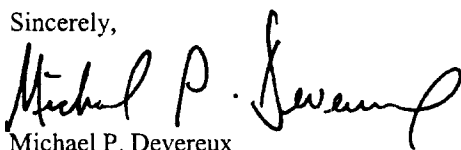
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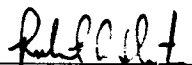
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	For restful nights and refreshing days with no morning grogginess.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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.

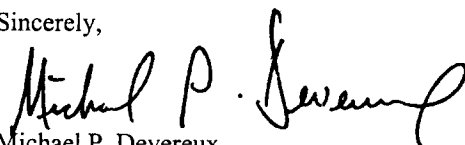
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January 6, 2006

Office of Nutritional Products, Labeling &  
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RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	A non-habit forming herbal blend to safely, gently and naturally help you sleep.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster  
Robert C. Doster  
Title: Senior Vice President of Scientific Affairs  
Date: 1/6/06

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Remifemin® Good Night	Clinically shown to safely and gently support your body's own long-term sleep pattern.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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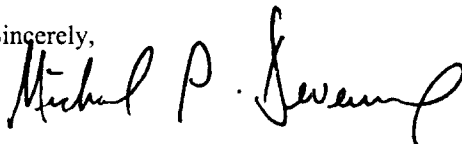
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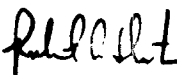
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Remifemin® Good Night	For a deep, high-quality sleep, naturally.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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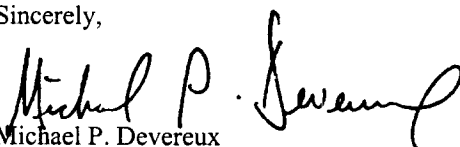
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	Rest well, Rest assured with Remifemin Good Night.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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.

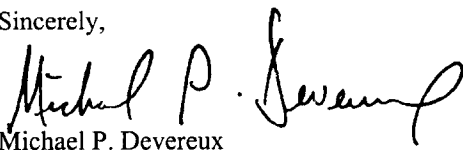
By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/6/06

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



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P: 920.469.9099 · F: 920.469.4418 (Phyto)

January 6, 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>
Remifemin® Good Night	Improve quality of restful sleep.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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.

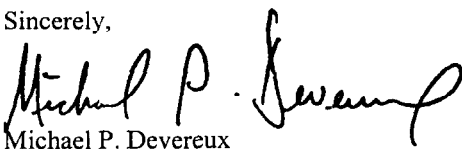
By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/6/06

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Sincerely,

  
Michael P. Devereux  
Chief Operations Officer



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January 6, 2006

Office of Nutritional Products, Labeling &  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	Good night's sleep, naturally.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/6/06

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



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	Natural relaxation to help you fall asleep.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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: 

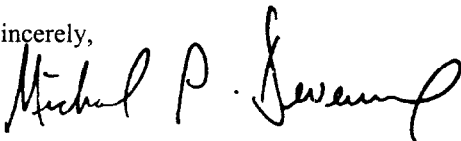
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/6/06

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Sincerely,



Michael P. Devereux  
Chief Operations Officer



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January 6, 2006

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	Normalize sleep patterns to help you stay asleep.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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: 

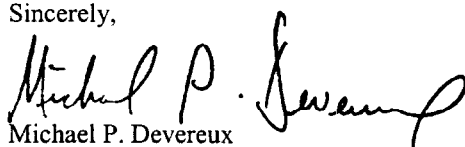
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/6/06

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Sincerely,

  
Michael P. Devereux  
Chief Operations Officer



# ENZYMATIC THERAPY

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January 7, 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:

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	Proven safe & effective relief: 70% reduction in menopausal symptoms.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/7/06

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







# ENZYMATIC THERAPY

LABORATORIES

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January 7, 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


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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin® Good Night	Remifemin Good Night works 2 ways for a good night's sleep – RemiSure™ Black Cohosh for night sweats and hot flashes.* It is also a special herbal blend for other causes of occasional sleeplessness*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

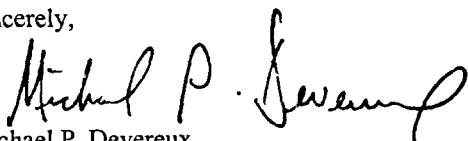
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-7-06

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.™

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## ENZYMATIC THERAPY®

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# ENZYMATIC THERAPY

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January 17, 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.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin® Good Night	Clinically proven safe and effective for a 70% reduction in symptoms including: hot flashes, night sweats, mood swings, occasional sleeplessness and anxiety.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

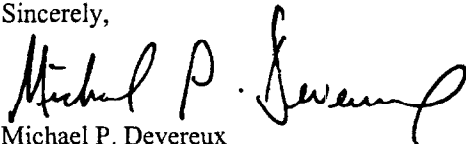
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-17-06

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.™

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## ENZYMATIC THERAPY™

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January 7, 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>
Remifemin® Good Night	One tablet at night, relieves menopausal symptoms plus helps you fall asleep and stay asleep, naturally.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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: 

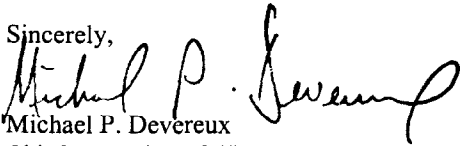
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/7/06

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



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January 7, 2006

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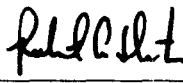
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	Proven relief from night sweats plus helps you sleep well.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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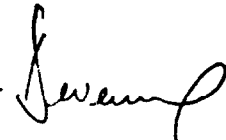
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# ENZYMATIC THERAPY

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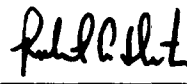
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	One tablet at bedtime, provides 24 hour relief from menopausal and occasional sleeplessness symptoms.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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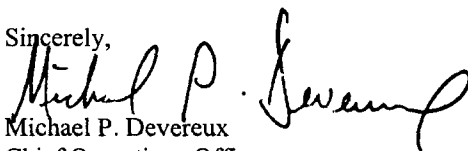
Robert C. Doster

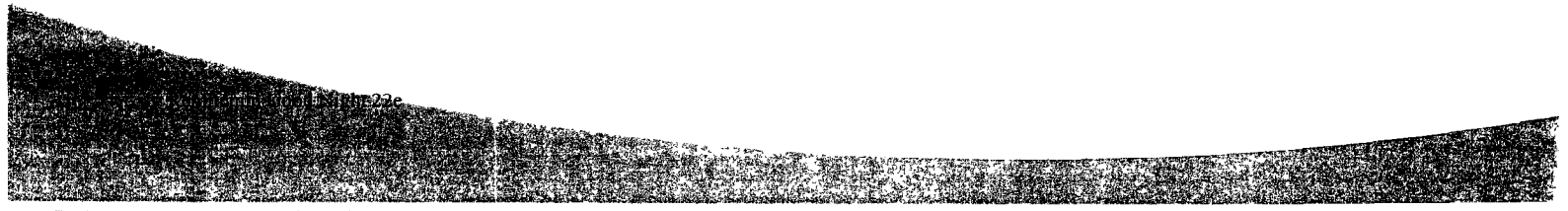
Title: Senior Vice President of Scientific Affairs

Date: 1/7/06

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Sincerely,

  
Michael P. Devereux  
Chief Operations Officer





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P: 920.469.9099 F: 920.469.4418 (Phyto)

January 7, 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>
Remifemin® Good Night	Sound Sleep and Brighter Days*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster  
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/7/06

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



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## INTEGRATIVE THERAPEUTICS INC.™

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&  
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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)

January 7, 2006

Office of Nutritional Products, Labeling &  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	A recent clinical study shows our exclusive, standardized extract of Black Cohosh provides a 70% reduction in hot flashes, night sweats, and mood swings.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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.

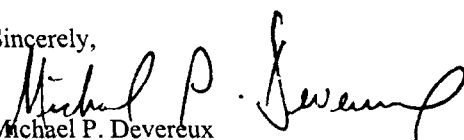
By:   
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Chief Operations Officer





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January 7, 2006

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<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Remifemin® Good Night	Contains clinically proven, estrogen-free standardized black cohosh, RemiSure™ that relieves menopausal symptoms.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

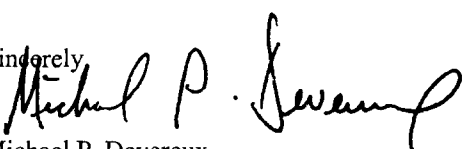
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Michael P. Devereux  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	Proven effective, natural and well tolerated.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster  
Robert C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 1/7/06

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Sincerely,  
Michael P. Devereux  
Michael P. Devereux  
Chief Operations Officer



# ENZYMATIC THERAPY

INCORPORATED

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January 7, 2006

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin® Good Night	Proven effective, RemiSure™ black cohosh is the most clinically studied natural intervention for menopause with over 40 years of use worldwide.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster  
Robert C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 1-7-06

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Michael P. Devereux  
Chief Operations Officer



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**PHYTOPHARMICA\***

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<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Remifemin® Good Night	RemiSure™ black cohosh, the most clinically studied natural treatment for relief of menopausal symptoms.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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.

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Date: 1-7-06

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin® Good Night	RemiSure™ black cohosh reduces perimenopausal and menopausal discomfort.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

1-7-06

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Chief Operations Officer



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January 7, 2006

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin® Good Night	Nearly 50 years of clinical studies show RemiSure™ black cohosh provides proven relief from hot flashes, night sweats, related occasional sleeplessness and mood swings associated with menopause.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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Michael P. Devereux  
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Chief Operations Officer

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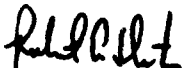
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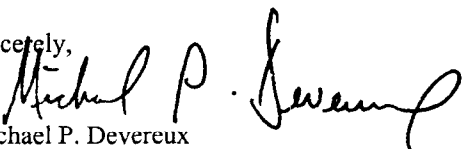
<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Remifemin® Good Night	RemiSure™ black cohosh, the #1 OB/GYN recommended non-prescription menopausal therapy.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster  
 Title: Senior Vice President of Scientific Affairs

Date: 1-7-06

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

Sincerely,  
  
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 Chief Operations Officer



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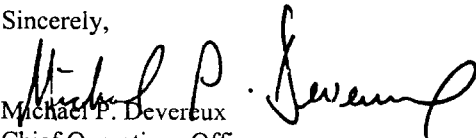
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	Remifemin Good Night doesn't have the side effects that are experienced with hormonal drugs prescribed for the relief of menopausal symptoms.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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Title: Senior Vice President of Scientific Affairs

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Remifemin® Good Night	A safe, natural alternative to HRT for the treatment of menopausal symptoms.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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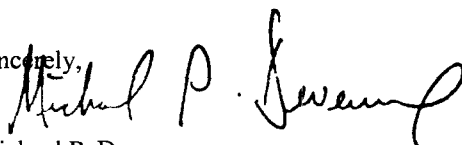
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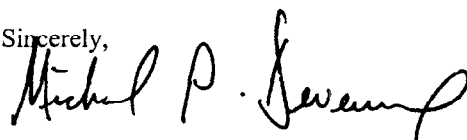
<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Remifemin® Good Night	The effectiveness of RemiSure™ black cohosh in the management of menopausal symptoms has been established from rigorous, well-controlled, clinical trials as well as open clinical monitoring trials in physician's practices studying over 1200 women in total.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 1-7-06

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.™**  
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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>
Remifemin® Good Night	A total of 304 women were randomly allocated to receive 40 mg of RemiSure™ black cohosh or matching placebo daily for 12 weeks. The results showed that women in the RemiSure™ black cohosh group experienced a significant decrease in hot flashes.* No significant adverse effects were reported	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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: 

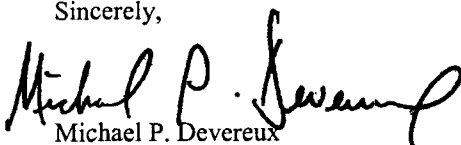
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-7-06

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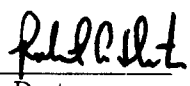
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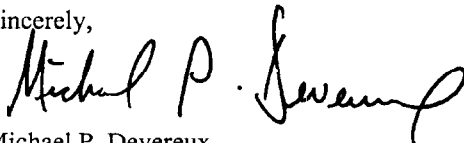
<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Remifemin® Good Night	Clinical studies of RemiSure™ black cohosh conclude that statistically significant improvement in all scales especially in early menopause.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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.

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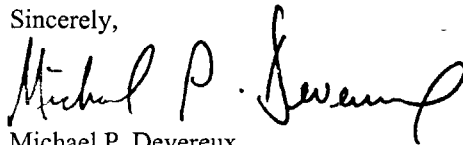
PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin® Good Night	Clinical studies of RemiSure™ black cohosh conclude that statistically significant improvement in all daily and weekly hot flashes.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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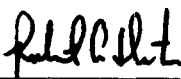
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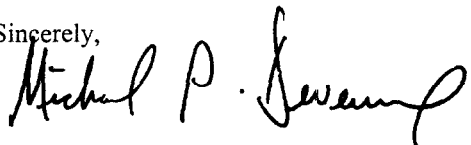
<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Remifemin® Good Night	A clinical study of RemiSure™ black cohosh found 80% improvement of menopausal symptoms.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster  
 Title: Senior Vice President of Scientific Affairs

Date: 1-7-06

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

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 Chief Operations Officer



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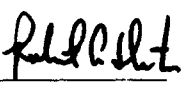
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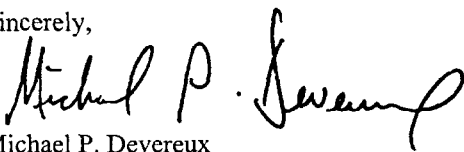
PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin® Good Night	RemiSure™ black cohosh works safely and effectively to treat menopause symptoms without affecting hormone levels or vaginal cytology (pap smear).*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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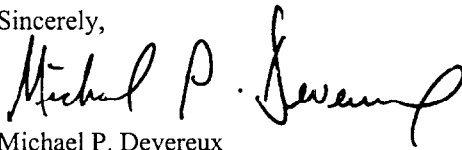
<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Remifemin® Good Night	RemiSure™ black cohosh decreased the physical symptoms of menopause by approximately 60% (Kupperman Menopausal Index).*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster  
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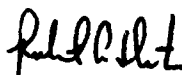
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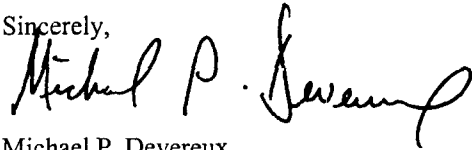
<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Remifemin® Good Night	Daily hot flashes decreased by 86% in the RemiSure™ black cohosh group (from 4.9 to 0.7 per day)† Emotional complaints were also dramatically reduced.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Remifemin® Good Night	RemiSure™ black cohosh effectively relieved menopausal symptoms, particularly in women in the early stage of menopause.* Most significant reduction was in hot flash occurrence.* Other symptoms resulting in significant reduction include; psyche (irritability and memory), and atrophy (vaginal dryness.)*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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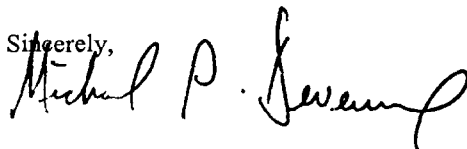
<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Remifemin® Good Night	RemiSure™ black cohosh reduced mean daily hot flash frequency by 50% after 4 weeks. Overall, participants reported less occasional sleeplessness, less fatigue, and fewer night sweats.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

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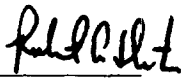
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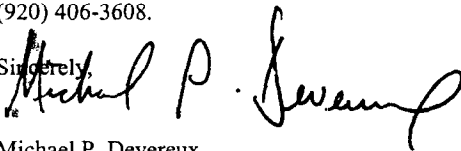
PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin® Good Night	Uncontrolled reports, postmarketing surveillance, and human clinical trials of more than 2,800 patients demonstrate a low incidence of adverse events (5.4%). Of the reported adverse events, 97% were minor and did not result in discontinuation of therapy, and the only severe events were not attributed to Cimicifuga treatment. Confirms the safety of specific Cimicifuga extracts, particularly isopropanolic preparations (RemiSure™ black cohosh), for use in women experiencing menopausal symptoms and as a safe alternative for women in whom estrogen therapy is contraindicated.	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster  
 Title: Senior Vice President of Scientific Affairs

Date: 1-7-06

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



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P: 920.469.9099 F: 920.469.4418 (Phyto)

January 17, 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.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin® Good Night	The most clinically tested brand for natural relief of menopause.*	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root 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 C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-17-06

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