

March 9, 2003

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Mr. Robert Moore Office of Nutritional Products, Labeling & Dietary Supplements, HFS 811 Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

Label Claims/Disclaimers RE:

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Hops: Key constituents of hops include a volatile oil, valerianic acid, phytoestrogenic substances, tannins, and flavonoids. Hops have been demonstrated to induce sleep.*

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:

Title: Senior Vice President of Scientific Affairs

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

Fatigued to Fantastic Revitalizing Sleep Formula 37e

978 0162

LET 11591

825 Challenger Drive Green Bay, WI 54311-8328

Fax: 888-570-6460

Ph: 920-469-1313

www.enzy.com



March 10, 2003

Mr. Robert Moore Office of Nutritional Products, Labeling & Dietary Supplements, HFS 811 Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

MAR 20 2003

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Wild Lettuce Powder and Extract: Supports restful sleep by promoting a relaxed feeling.*

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 C. Doster

Title: Senior Vice President of Scientific Affairs

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

Sincerely,

Michael P. Devereux

Ph: 920-469-1313 Chief Financial Officer

Fatigued to Fantastic Revitalizing Sleep Formula 38e

825 Challenger Drive Green Bay, WI 54311-8328

Fax: 888-570-6460

www.enzy.com



February 18, 2003

Mr. Robert Moore Office of Nutritional Products, Labeling & Dietary Supplements, HFS 811 Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740



RE:

Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantasticl® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Fatigued to Fantastic!® Revitalizing Sleep Formula is a combination of herbal ingredients that promote relaxation and restful sleep.*

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.

Title: Senior Vice President of Scientific Affairs

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

Michael P. Devereux

Chief Financial Officer

Green Bay, WI 54311-8328

825 Challenger Drive

Ph: 920-469-1313 Fax: 888-570-6460

www.enzy.com

Fatigued to Fantastic Revitalizing Sleep Formula 18e



February 19, 2003

Mr. Robert Moore Office of Nutritional Products, Labeling & Dietary Supplements, HFS 811 Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

Label Claims/Disclaimers RE:

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

Man 2 0 2003

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Valerian (Valeriana officinalis) root extract is included in Fatigued to Fantastic! Revitalizing Sleep Formula to support better sleep at night.* It has been clinically studied for its ability to support sleep.*

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.

Title: Senior Vice President of Scientific Affairs

Date: 2/19/03

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

Michael P. Jeven

Green Bay, WI 54311-8328

Ph: 920-469-1313

825 Challenger Drive

Fax: 888-570-6460

www.enzy.com

Michael P. Devereux Chief Financial Officer

Fatigued to Fantastic Revitalizing Sleep Formula 19e



February 20, 2003

Mr. Robert Moore Office of Nutritional Products, Labeling & Dietary Supplements, HFS 811 Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

MAR 2 0 2003

Label Claims/Disclaimers RE:

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Fatigued to	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Valerian root extract has been reported to have sleep inducing and calming effects in in- vivo studies and clinical trials.*

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 C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/20/03

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

Sincerely.

Chief Financial Officer

825 Challenger Drive Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Fatigued to Fantastic Revitalizing Sleep Formula 20e



February 21, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



RE:

Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	A placebo-controlled, crossover trial of 128 volunteers reported that valerian extract taken at bedtime led to improved sleep quality, decreased sleep latency, and reduced the number of night awakenings.*

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:

2/21/03

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

Sincerely,

825 Challenger Drive Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Michael P. Devereux Chief Financial Officer

Fatigued to Fantastic Revitalizing Sleep Formula 21e

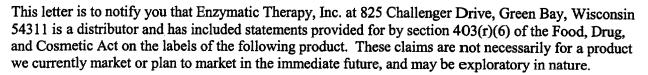


February 22, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:



COMPANY	PRODUCT NAME	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Two other clinical studies using valerian before bedtime also demonstrated improved sleep quality.*

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: KLIPCI

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/22/03

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

825 Challenger Drive Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Fatigued to Fantastic Revitalizing Sleep Formula 22e



February 23, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

MAR 8 0 2009

RE:

Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	In a double-blind, cross- over, placebo-controlled trial, subjective sleep latency and wake time after sleep-onset were 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.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date:

2/23/03

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

Singerely, Muchael P. Neward

Michael P. Devereux Chief Financial Officer

Green Bay, WI 54311-8328 Ph: 920-469-1313

825 Challenger Drive

Fax: 888-570-6460

www.enzy.com

Fatigued to Fantastic Revitalizing Sleep Formula 23e



February 24, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantasticl® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	One electroencephalographical (EEG) study reported that valerian, taken three times daily, improved deep sleep (stages 3 and 4) and decreased stage 1 sleep.*

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: Kild

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date:

2/24/03

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

825 Challenger Drive Green Bay, Wi 54311-8328

> Ph: 920-469-1313 Fax: 888-570-6460

www.enzy.com



February 25, 2003

Dear Mr. Moore:

Mr. Robert Moore Office of Nutritional Products, Labeling & Dietary Supplements, HFS 811 Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantasticl® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Recently, two human trials also demonstrated that valerian extract was effective in improvement of sleep structure and perception in subjects.*

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 C. Doster

Title: Senior Vice President of Scientific Affairs

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

Michael P. Devereux Chief Financial Officer

Green Bay, WI 54311-8328 Ph: 920-469-1313

825 Challenger Drive

Fax: 888-570-6460

www.enzy.com

Fatigued to Fantastic Revitalizing Sleep Formula 25e



February 26, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantasticl® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L- Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Passionflower extract has been reported to have calming effects in clinical trials.* A recent double-blind randomized controlled trial of 36 volunteers reported that passionflower extract is effective in calming restlessness.*

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: Thirtis

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/2/6/03

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

Sincerely,

825 Challenger Drive Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Michael P. Devereux Chief Financial Officer

Fatigued to Fantastic Revitalizing Sleep Formula 26e

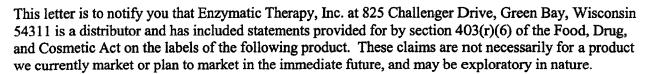


February 27, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:



Mar 2 C 2009

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantasticl® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	The key ingredient in green tea that provides health benefits is I-theanine.*

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. Poster

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date:  $\frac{2/27/03}{}$ 

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

Sincerel

Michael P. Devereux Chief Financial Officer

825 Challenger Drive Green Bay, WI 54311-8328 Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Fatigued to Fantastic Revitalizing Sleep Formula 27e

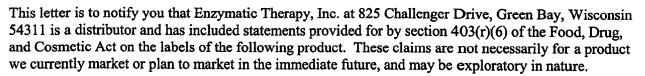


February 28, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:



<u>COMPANY</u>	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	In clinical trials, L-theanine causes significant increases of certain neurotransmitter concentrations in brain, such as serotonin and dopamine, which promotes muscle relaxation and improves sleep.*

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.

Bv:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/28/03

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

Sincerely,

825 Challenger Drive Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Michael P. Devereux Chief Financial Officer

Fatigued to Fantastic Revitalizing Sleep Formula 28e

March 1, 2003

Mr. Robert Moore Office of Nutritional Products, Labeling & Dietary Supplements, HFS 811 Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740



RE: Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug. and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L- Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	In a recent study, the brain activity of 50 volunteers was measured after the oral administration of 50-200 mg of L-theanine. L-theanine promoted the generation of alpha-brain waves, considered to be an index of relaxation, in the volunteers.* This study concluded that L-theanine promotes relaxation in humans by increasing alpha brain waves.*

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.

Title: Senior Vice President of Scientific Affairs

825 Challenger Drive Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Fatigued to Fantastic Revitalizing Sleep Formula 29e

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

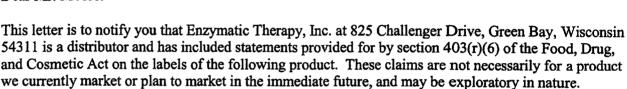
NATURAL MEDICINES

March 2, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:



MAR 2 0 2003

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Hops flower (Humulus lupulus) extract has been studied for its ability to calm restlessness and can be used to support restful sleep.*

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: FLICILL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/2/23

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

Ph: 920-469-1313 Fax: 888-570-6460

825 Challenger Drive Green Bay, WI 54311-8328

www.enzy.com

Fatigued to Fantastic Revitalizing Sleep Formula 30e

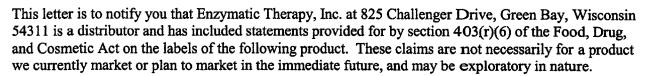
NATURAL MEDICINES

March 3, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:



COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Hops have been used for centuries for gastrointestinal health support, and have more recently been used to support healthy sleep.*

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: FLICILE

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/3/03

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

Ph: 920-469-1313 Fax: 888-570-6460

825 Challenger Drive Green Bay, WI 54311-8328

www.enzy.com

Fatigued to Fantastic Revitalizing Sleep Formula 31e

NATURAL MEDICINES

March 4, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Mr. Moore:



This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Hops have been demonstrated to induce sleep.*

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: KINCIL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/4/03

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

Sincerely

Green Bay, WI 54311-8328

825 Challenger Drive

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Michael P. Devereux Chief Financial Officer

Fatigued to Fantastic Revitalizing Sleep Formula 32e

NATURAL MEDICINES®

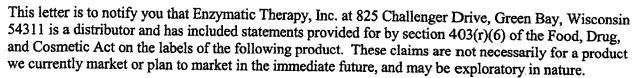
March 5, 2003

Mr. Robert Moore Office of Nutritional Products, Labeling & Dietary Supplements, HFS 811 Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Mr. Moore:



COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Wild lettuce (Lactuca virosa) extract and powder have been used in traditional medicine for its calmative effect.*

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.

Title: Senior Vice President of Scientific Affairs

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

825 Challenger Drive reen Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Michael P. Devereux Chief Financial Officer

Fatigued to Fantastic Revitalizing Sleep Formula 33e

NATURAL MEDICINES®

March 6, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:



This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantastic!® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	Jamaica Dogwood (Piscidia piscipula) root extract contains isoflavonoids and tannins that help promote restful sleep.*

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: KLICK

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/a/0.3

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

Sincerely,

825 Challenger Drive en Bay, WI 54311-8328

en bay, wi 54311-83*2*8

Ph: 920-469-1313 Fax: 888-570-6460

www.enzy.com

Michael P. Devereux Chief Financial Officer

Fatigued to Fantastic Revitalizing Sleep Formula 34e

NATURAL MEDICINES®

March 7, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



RE:

Label Claims/Disclaimers

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantasticl® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	This herb helps individuals fall asleep, and promotes musculoskeletal relaxation.*

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: Kildl

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/1/05

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

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Michael P. Devereux Chief Financial Officer

Fatigued to Fantastic Revitalizing Sleep Formula 35e

**NATURAL MEDICINES®** 

March 8, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Mr. Moore:



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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Fatigued to Fantastick® Revitalizing Sleep Formula	Valerian Root Extract, Passionflower Leaf and Flower Extract, L-Theanine, Hops Flower Extract, Wild Lettuce Leaf Extract, Jamaica Dogwood Root Extract, Wild Lettuce Leaf	This botanical ingredient has also been found to resolve nervous irritability, thus promoting quality sleep.*

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: 3/8/03

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

Sincerely,

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Ph: 920-469-1313

Fax: 888-570-6460

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Michael P. Devereux Chief Financial Officer

Fatigued to Fantastic Revitalizing Sleep Formula 36e