

# Enzymatic Therapy

NATURAL MEDICINES®

October 8, 2003

705 RECEIVED 10/15/03 21:27

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

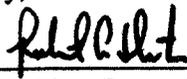
RE: Label Claims/Disclaimers

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.	Escalation®	Bitter Orange (Citrus x aurantium) Fruit Extract, Cola (Cola nitida) Nut Extract, Green Tea (Camellia sinensis) Leaf Extract	The cola nut extract and green tea leaf extract in this formula support overall health, physical stamina, and boost energy levels.*

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: 10/8/03

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

Escalation 6c

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13226

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# Enzymatic Therapy

NATURAL MEDICINES®

October 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

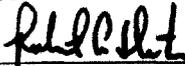
RE: Label Claims/Disclaimers

Dear Mr. Moore:

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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Escalation®	Bitter Orange (Citrus x aurantium) Fruit Extract, Cola (Cola nitida) Nut Extract, Green Tea (Camellia sinensis) Leaf Extract	The bitter orange fruit extract contains an alkaloid, synephrine, which has thermogenic properties and boosts metabolic rates.*

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: 10/8/03

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

Escalation 7c

# Enzymatic Therapy

NATURAL MEDICINES®

October 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

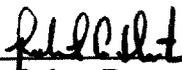
RE: Label Claims/Disclaimers

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Escalation®	Bitter Orange (Citrus x aurantium) Fruit Extract, Cola (Cola nitida) Nut Extract, Green Tea (Camellia sinensis) Leaf Extract	Similar in structure to ephedrine, synephrine may suppress appetite and increase metabolic rate without serious negative side effects.*

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.

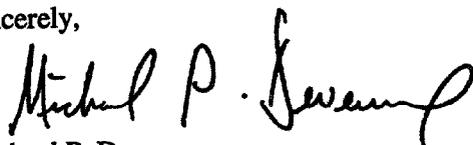
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/8/03

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

Escalation 8e

# Enzymatic Therapy

NATURAL MEDICINES®

October 9, 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

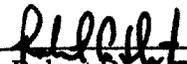
RE: Label Claims/Disclaimers

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.	Escalation®	Bitter Orange (Citrus x aurantium) Fruit Extract, Cola (Cola nitida) Nut Extract, Green Tea (Camellia sinensis) Leaf Extract	In clinical studies, bitter orange has been found to increase resting metabolic rates, which can lead to promotion of weight loss.*

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: 10/9/03

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

# Enzymatic Therapy

NATURAL MEDICINES®

October 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

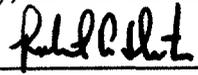
RE: Label Claims/Disclaimers

Dear Mr. Moore:

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Escalation®	Bitter Orange (Citrus x aurantium) Fruit Extract, Cola (Cola nitida) Nut Extract, Green Tea (Camellia sinensis) Leaf Extract	In an eight week study, the effect of bitter orange extract was measured. The authors concluded that bitter orange extract induced a significant increase in resting metabolic rate, as well as increasing metabolic rate after ingestion of a meal.*

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: 10/10/03

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Escalation 10e

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

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized "M" and "D".

Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

October 11, 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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Escalation®	Bitter Orange (Citrus x aurantium) Fruit Extract, Cola (Cola nitida) Nut Extract, Green Tea (Camellia sinensis) Leaf Extract	Another clinical study determined the effect of bitter orange extract on body composition and metabolic rates. In this randomized, double-blind, placebo-controlled study, participants received either a combination of bitter orange extract and caffeine, or placebo. Compared to subjects in the placebo and control groups, subjects in the treatment group experienced a 3.1 lb loss of body weight, corresponding to a significant reduction in body mass (BMI). This study concluded that the combination of bitter orange extract and caffeine is safe and effective when combined with caloric restriction and exercise for promoting weight loss in healthy overweight adults.*

825 Challenger Drive

Green Bay, WI 54311-8328

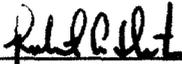
Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Escalation 11e

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: 10/11/03

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

# Enzymatic Therapy

NATURAL MEDICINES®

October 12, 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

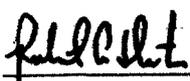
RE: Label Claims/Disclaimers

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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Escalation®	Bitter Orange (Citrus x aurantium) Fruit Extract, Cola (Cola nitida) Nut Extract, Green Tea (Camellia sinensis) Leaf Extract	Cola Nut Extract : Caffeine has been extensively studied as an ergogenic (energy producing) aid.*

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: 10/12/03

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

Escalation 12e

# Enzymatic Therapy

NATURAL MEDICINES\*

October 13, 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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Escalation®	Bitter Orange (Citrus x aurantium) Fruit Extract, Cola (Cola nitida) Nut Extract, Green Tea (Camellia sinensis) Leaf Extract	Cola Nut Extract: In one clinical study, the ingestion of caffeine prior to exercise increased physical performance during prolonged endurance exercise and short-term intense exercise.*

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: 10/13/03

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

Escalation 13e

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

# Enzymatic Therapy

NATURAL MEDICINES®

October 14, 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

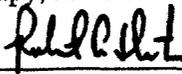
RE: Label Claims/Disclaimers

Dear Mr. Moore:

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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Escalation®	Bitter Orange (Citrus x aurantium) Fruit Extract, Cola (Cola nitida) Nut Extract, Green Tea (Camellia sinensis) Leaf Extract	Many components of green tea have been found to have numerous biological activities that are supportive of human health.* One component of green tea that has demonstrated health benefits is caffeine.*

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: 

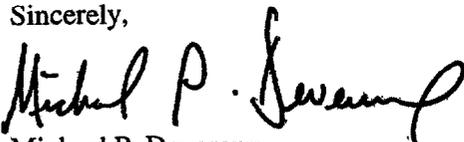
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/14/03

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

Escalation 14e

# Enzymatic Therapy

NATURAL MEDICINES®

October 15, 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

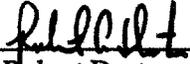
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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Escalation®	Bitter Orange (Citrus x aurantium) Fruit Extract, Cola (Cola nitida) Nut Extract, Green Tea (Camellia sinensis) Leaf Extract	Like cola nut, the caffeine in green tea has ergogenic effects and is effective in boosting energy levels and physical performance.* In addition to its ergogenic benefits, clinical studies have shown that green tea works synergistically with caffeine to boost thermogenesis (calorie burning).*

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: 10/15/03

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Escalation 15e

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

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, prominent initial "M".

Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

October 16, 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

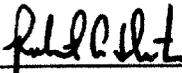
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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Escalation®	Bitter Orange (Citrus x aurantium) Fruit Extract, Cola (Cola nitida) Nut Extract, Green Tea (Camellia sinensis) Leaf Extract	In a recent study, the effects of green tea extract were evaluated in moderately obese patients. After 3 months, body weight of the patients was decreased by 4.6% and waist circumference by 4.48%. These results suggest the green tea extract to be a natural weight loss product, which exerts its activity by several ways, including inhibition of lipases and stimulation of thermogenesis.*

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: 10/16/03

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

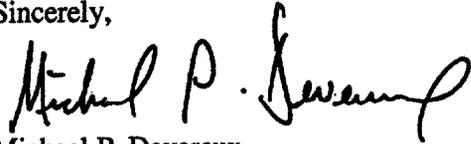
Fax: 888-570-6460

www.enzy.com

Escalation 16e

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

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux  
Chief Financial Officer