

February 23, 2003

1729 '03 APR -4 P4:28

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. | Vitaline® L-Carnitine | L-Carnitine | Vitaline® L-Carnitine is a dietary supplement for support of L-carnitine affected physical systems, including support of cardiac, renal (kidney), and immune health.* |

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: KLYCK

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: $\frac{2}{23}/03$

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

Vitaline L-Carnitine 3e

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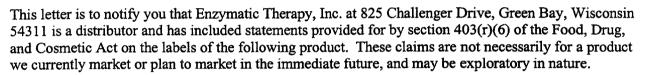
February 24, 2003

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:



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| COMPANY | PRODUCT NAME | DIETARY INGREDIENTS | STATEMENTS |
|----------------------------|--------------------------|------------------------|--|
| Enzymatic Therapy, Inc. | Vitaline® L-Carnitine | L-Carnitine | The primary function of carnitine is to carry long-chain fatty acids across the inner mitochondrial membrane and shuttle acetyl groups out of the mitochondria.* |

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: 2/24/03

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

Ph: 920-469-1313

825 Challenger Drive

Fax: 888-570-6460

www.enzy.com

Michael P. Devereux Chief Financial Officer

Vitaline L-Carnitine 4e



February 25, 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. | Vitaline® L-Carnitine | L-Carnitine | L-carnitine supports healthy microcirculation and tissue oxygen delivery in the kidney, as well as healthy serum albumin concentration.* |

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

Title: Senior Vice President of Scientific Affairs

P. Nevemp

Date: _2/25/03

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

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

825 Challenger Drive Green Bay, WI 54311-8328

www.enzv.com

Vitaline L-Carnitine 5e

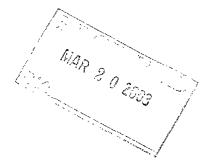


February 26, 2003

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 | STATEMENTS |
|----------------------------|--------------------------|------------------------|--|
| Enzymatic Therapy, Inc. | Vitaline® L-Carnitine | L-Carnitine | L-carnitine supports immune health, including support of cytokine response and lymphocyte response.* |

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: 2/26/03

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

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

Fax: 888-570-6460

825 Challenger Drive

www.enzy.com

Vitaline L-Carnitine 6e



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:

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. | Vitaline® L-Carnitine | L-Carnitine | L-carnitine supplementation supports healthy cardiac enzyme levels, heart contractility and subsequent circulation and exercise tolerance, because of the special role L-carnitine plays in transporting fatty acids into the cell for energy production.* |

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:

Pohert Doster

Title: Senior Vice President of Scientific Affairs

Date: $\frac{2/21}{03}$

825 Challenger Drive

Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Vitaline L-Carnitine 7e

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



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:

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| COMPANY | PRODUCT NAME | DIETARY INGREDIENTS | STATEMENTS |
|----------------------------|--------------------------|------------------------|--|
| Enzymatic Therapy, Inc. | Vitaline® L-Carnitine | L-Carnitine | L-carnitine transports fatty acids into the mitochondrial matrix for oxidation and supports healthy glucose 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: $\frac{2/28/03}{}$

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

Vitaline L-Carnitine 8e