

January 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

FEB 25273

1276 '03 MAR 19 P2:26

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.	Healthy Cells™ Prostate	Calcium D-Glucarate, Selenium, Broccoli Floret and Stalk Concentrate, Green Tea Leaf Extract, Maitake Mushroom Powder, Maitake Mushroom Extract, Lycopene	As a part of the Healthy Cells™ line, Healthy Cell's Prostate can be used alone or in combination with Cell Forte® with IP-6 and Inositol for cellular health and support.*

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: 1/16/03

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

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83757

825 Challenger Drive Green Bay, WI 54311-8328

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

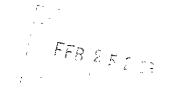
www.enzy.com

Healthy Cells Prostate 7e



February 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



RE:

Label Claims/Disclaimers

Dear Mr. Moore:

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COMPANY	PRODUCT	DIETARY	STATEMENIS
	NAME	INGREDIENTS	11 Programme
Enzymatic Therapy, Inc.	Healthy Cells™ Prostate	Calcium D-Glucarate, Selenium, Broccoli Floret and Stalk Concentrate, Green Tea Leaf Extract, Maitake Mushroom Powder, Maitake Mushroom Extract, Lycopene	Calcium D-glucarate (CGT) is a precursor of glucarolactone (GL), which inhibits β-glucuronidase. By inhibition of β-glucuronidase, GL increases the amount of these compounds sequestered and excreted as the glucuronides, thus decreasing the portion of active compounds that could be hazardous to the body. In animal studies, administration of CGT was reported to inhibit β-glucuronidase activity. CGT was also found to support healthy cell development.*

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: 2/16/03

825 Challenger Drive

Green Bay, WI 54311-8328

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

www.enzy.com

Healthy Cells Prostate 31e

Sincerely,



February 17, 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.	Healthy Cells™ Prostate	Calcium D-Glucarate, Selenium, Broccoli Floret and Stalk Concentrate, Green Tea Leaf Extract, Maitake Mushroom Powder, Maitake Mushroom Extract, Lycopene	In the early 1990's, broccoli was found to increase the activity of Phase II enzymes. Later, sulforaphane was identified as the principal Phase II enzyme inducer in broccoli extract. In animal studies, sulforaphane was reported to enhance chemical detoxification and support healthy cell development.*

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: KLYCUL

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/17/03

825 Challenger Drive Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Healthy Cells Prostate 32e

Sincerely,



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	STATEMENTS
Enzymatic Therapy, Inc.	Healthy Cells™ Prostate	Calcium D-Glucarate, Selenium, Broccoli Floret and Stalk Concentrate, Green Tea Leaf Extract, Maitake Mushroom Powder, Maitake Mushroom Extract, Lycopene	Animal studies have shown that the consumption of tea and its polyphenols afford healthy supportive benefits.*

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: KTACIK

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/18/03

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

Healthy Cells Prostate 33e



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

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.	Healthy Cells™ Prostate	Calcium D-Glucarate, Selenium, Broccoli Floret and Stalk Concentrate, Green Tea Leaf Extract, Maitake Mushroom Powder, Maitake Mushroom Extract, Lycopene	Maitake D-fraction is a mixture of β-D-glucan fraction obtained from maitake water extracts. It mainly contains β-1,6' D-glucan with β-1,3' branches. In an animal model, D-fraction was shown to activate macrophages, natural killer cells and cytotoxic T-cells with a concomitant increase in interleukin-1 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: KUURUH

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/19/03

825 Challenger Drive Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Healthy Cells Prostate 34e

Sincerely, Leven



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

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	DIE ARY INGREDIENTS	SIAIEMENIS
Enzymatic Therapy, Inc.	Healthy Cells™ Prostate	Calcium D-Glucarate, Selenium, Broccoli Floret and Stalk Concentrate, Green Tea Leaf Extract, Maitake Mushroom Powder, Maitake Mushroom Extract, Lycopene	Consumption of lycopene rich food, as well as higher concentrations of blood lycopene, is associated with a healthy prostate.*

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

Date: 2/20/03

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

Healthy Cells Prostate 35e



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.

<u>COMPANY</u>	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Healthy Cells™ Prostate	Calcium D-Glucarate, Selenium, Broccoli Floret and Stalk Concentrate, Green Tea Leaf Extract, Maitake Mushroom Powder, Maitake Mushroom Extract, Lycopene	The mechanism by which lycopene might support prostate health remains unclear. Lycopene is a potent antioxidant and efficiently neutralizes single oxygen and free radicals.* It also enhances the expression of gap-junction proteins involved in cell-cell communication. Finally, lycopene may protect cellular components such as DNA from specific types of damage from free radicals.*

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: KLICKL

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/21/03

825 Challenger Drive

Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

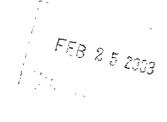
www.enzy.com

Healthy Cells Prostate 36e

Sincerely,



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:

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.	Healthy Cells™ Prostate	Calcium D-Glucarate, Selenium, Broccoli Floret and Stalk Concentrate, Green Tea Leaf Extract, Maitake Mushroom Powder, Maitake Mushroom Extract, Lycopene	Selenium is an essential trace element, which is found in food. It is a key component of glutathione peroxidase, which removes hydrogen peroxide and lipid hydroperoxides generated by free radicals and oxygen derived species. When selenium is deficient, the activity of glutathione peroxidase will be impaired, which may lead to accumulation of lipid hydroperoxides.*

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: 2/22/03

825 Challenger Drive Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Healthy Cells Prostate 37e

Sincerely,