

February 20, 2002

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U. S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

Label Claims/Disclaimers RE:

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer 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.

0

COMPANY	PRODUCT NAME	<u>DIETARY</u> INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Black Cohosh	Black Cohosh	Black cohosh has been clinically studied for more than 40 years for its ability to reduce menopausal discomfort.*

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: 2/20/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Black Cohosh 5e

Chief Financial Officer

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

825 Challenger Drive Green Bay, WI 54311-8328

www.enzy.com

978 0162 LET 956 6



March 11, 2002

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U. S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer 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.

COMPANY	PRODUCT NAME	<u>DIETARY</u> INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Black Cohosh	Black Cohosh	Black Cohosh delivers relief from menopausal symptoms including hot flashes, night sweats, and mood swings.*

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: 1/all. Wal

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/11/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely

Michael P. Devereux Chief Financial Officer

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

825 Challenger Drive

Fax: 888-570-6460

www.enzv.com

Black Cohosh 2e



February 21, 2002

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U. S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer 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.

COMPANY	PRODUCT NAME	<u>DIETARY</u> INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Black Cohosh	Black Cohosh	Black cohosh relieves menopausal symptoms, including hot flashes, night sweats, and mood swings.*

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) 469-3608.

Sincerely,

Chief Financial Officer

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

825 Challenger Drive

Fax: 888-570-6460

www.enzy.com

Black Cohosh 4e



March 14, 2002

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U. S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer 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.

COMPANY	PRODUCT NAME	<u>DIETARY</u> INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Black Cohosh	Black Cohosh	Black cohosh has been clinically studied for more than 40 years for its ability to reduce menopausal discomfort.*

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: 3/14/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

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

Black Cohosh 5e



March 12, 2002

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U. S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer 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.

COMPANY	PRODUCT NAME	<u>DIETARY</u> INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Black Cohosh	Black Cohosh	Dietary Supplement to relieve menopausal symptoms*

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) 469-3608.

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

Black Cohosh 3e