

SOFT GEL

TECHNOLOGIES, INC.™

January 7, 2002

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JAN 14 2003
BY:

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW; Washington, DC 20204

Dear Mr. Foret:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 343(r)(6)) and Section 101.93 of FDA's regulations (21 C.F.R.), we hereby notify you that we are using the following statements for the dietary supplement Venetron™, which is an extract from *Apocynum venetum* L:

- (1) Venetron™ maintains emotional well-being
- (2) Venetron™ supports feelings of well-being
- (3) Venetron™ helps to enhance mood
- (4) Venetron™ promotes a positive mood and enhances mental vitality
- (5) Venetron™ supports positive mental outlook

Soft Gel Technologies at 6982 Bandini Boulevard, Los Angeles, CA 90040, is the distributor of the dietary supplement Venetron™

The undersigned certifies that the information contained in this notice is complete and accurate, and that Soft Gel Technologies Inc. has substantiation (Butterweck V. et al. Antidepressant effects of *Apocynum venetum* leaves in a forced swimming test. Biol. Pharm. Bull 2001; 24:848) that these statements are truthful and not misleading.

Sincerely yours,

Yousry Naguib

Yousry Naguib, Ph.D.
Soft Gel Technologies Inc.

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EnzymaticTherapy®

NATURAL MEDICINES™

January 6, 2003

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

JAN 9 4 2003

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 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.	ProstaMed®	Saw Palmetto (Serenoa repens) Berry Extract	ProstaMed® is the standardized extract used in studies linking saw palmetto berry and prostate 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: Robert C. Doster

Robert C. 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

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

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