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FEB - 3 2003

Mr. Michael P. Devereux
Chief Financial Officer
Enzymatic Therapy, Inc.
825 Challenger Drive
Green Bay, Wisconsin 54311

Dear Mr. Devereux:

This is in response to your letter of January 11, 2003 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Enzymatic Therapy, Inc. is making the following claim, among others, for the product **Sea Buddies™ Immune Defense**:

“Children’s immune systems function to prevent infection, prevent pathogen replication, and eliminate infectious organisms.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease, namely infectious diseases caused by pathogenic microorganisms¹. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

¹In the preamble to the January 6, 2000 final rule on structure/function claims (65 FR 1000 at 1028; see discussion for section Q), FDA discussed when a claim about the role of a dietary supplement or dietary ingredient in the body’s response to disease or disease vector would be a disease claim.

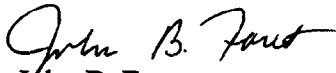
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Please contact us if we may be of further assistance.

Sincerely yours,



John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-MW340

EnzymaticTherapy®

NATURAL MEDICINES™

January 11, 2003

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

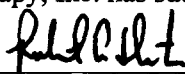
RE: Label Claims/Disclaimers

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Sea Buddies™ Immune Defense	Vitamin A, Vitamin C, Vitamin B6, Zinc, European Black Elderberry Fruit Extract	Children's immune systems function to prevent infection, prevent pathogen replication, and eliminate infectious organisms.*

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.

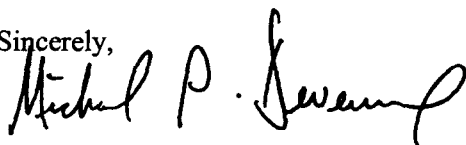
By: 
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/03

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

Sea Buddies Immune Defense 6e

825 Challenger Drive
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax 888-570-6460

www.enzy.com

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