



DEC - 8 2006

1533 6 10 18 P2 43

Mr. Michael P. Devereux
Chief Operating Officer
Enzymatic Therapy, Inc.
825 Challenger Drive
Green Bay, Wisconsin 54311-8328

Dear Mr. Devereux:

This is in response to your letter of November 10, 2006 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)) for the product LevLife™ Synergy Drink Mix

21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, a dietary supplement does not include a product represented for use as a conventional food or as a sole item of a meal or the diet. 21 U.S.C. 321(ff)(2)(B). The product identified above appears to be represented for use as a conventional food (i.e., it is identity labeled as a "drink mix." Therefore, in that it appears to be represented for use as a conventional food (i.e., a drink or beverage), it does not appear to be a dietary supplement within the meaning of 21 U.S.C. 321(ff) and claims made for it are not subject to 21 U.S.C. 343(r)(6).

Instead, this product appears to be a conventional food that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, it must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the product in its labeling if they are claims defined by 21 U.S.C. 343(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market this product as a conventional food and you have any questions about the status of any of its ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

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Please contact us if you require further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph..D.
Acting Director
Division of Dietary Supplement Programs
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-310

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

FDA, Minneapolis District Compliance, HFR-CE840



825 Challenger Drive • Green Bay, WI 54311-8328
 P: 920.469.1313 • F: 920.469.4400



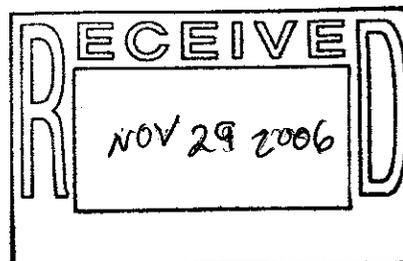
9 Monroe Parkway, Suite 250 • Lake Oswego, OR 97035
 P: 800.931.1709 • F: 503.349.4599



825 Challenger Drive • Green Bay, WI 54311-8328
 P: 920.469.9099 • F: 920.469.4418

November 10, 2006

Office of Nutritional Products, Labeling &
 Dietary Supplements, HFS 810
 Center for Food Safety and Applied Nutrition
 Food and Drug Administration
 5100 Paint Branch Parkway
 College Park, MD 20740



RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. 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.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
LevelLife™ Synergy Drink Mix	<p>Provides consistent energy*</p> <p>Balanced Blood Sugar = Consistent Energy*</p> <p>LevelLife products, Daily Sugar Regulator* and our Synergy Drink Mix, work together as a system to optimize your body's use of blood sugar and insulin for more consistent energy.*</p> <p>LevelLife products, Daily Sugar Regulator* and our Synergy Drink Mix, have been clinically shown to rebalance blood sugar levels in just 30 days.*</p> <p>LevelLife Daily Sugar Regulator helps to balance glucose levels.*</p> <p>Regain blood sugar balance for natural consistent energy.*</p> <p>Get off the blood sugar seesaw and get consistent energy.*</p> <p>LevelLife™ Synergy Drink Mix stimulates you body's natural energy production for balanced energy release.*</p> <p>LevelLife™ Synergy Drink Mix helps to control sugar and carbohydrate cravings.*</p> <p>LevelLife™ Synergy Drink Mix curbs your between meal cravings and delivers long-lasting energy without stimulants.*</p> <p>Work naturally with the body's energy management system.*</p> <p>LevelLife™ Synergy Drink Mix promotes long lasting balanced release energy.*</p> <p>Boosts craving resistance.*</p>	<p>Taurine, Beneo Synergy 1, Whey Protein, Glucomannan Extract, Chromium (Picolinate) (Chromax), Malic Acid, Hesperidin Complex 50% (from citrus fruits), Vitamin C (Ascorbic Acid), L-Tyrosine, Glycine, Riboflavin, Inositol</p>

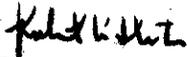
LevelLife Synergy Drink Mix 1e

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06-8828

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: 11/10/06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Operating Officer