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NOV 28 2006

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

Dear Mr. Devereux:

This is in response to your letters of November 8 and 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 products Liquid Calcium Magnesium with Botanicals and ITI Mega Multi Vitamin Drink Mix. Your November 8, 2006 submission states that Liquid Calcium Magnesium with Botanicals is using the claim "Liquid Calcium Magnesium with Botanicals...may reduce the risk of osteoporosis."

This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in these regulations may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis. If an osteoporosis prevention claim is made for a dietary ingredient other than calcium, then such a claim would be outside the scope of the authorized health claim and would appear to be a disease claim that would cause the product to be a drug under 21 U.S.C. 321(g)(1)(B).

You also made a submission for the product ITI Mega Multi Vitamin 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).

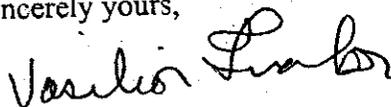
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Page 2 - Mr. Michael P. Devereux

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.

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



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  
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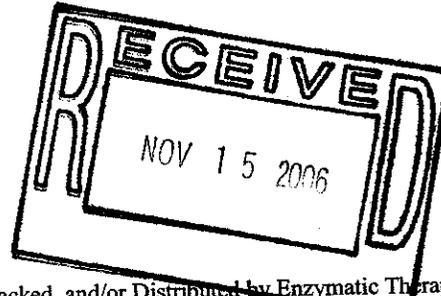
825 Challenger Drive • Green Bay, WI 54311-8328  
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November 10, 2006

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(g)(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
ITI Mega Multi Vitamin Drink Mix	Combined with additional ingredients, including natural fruit extract antioxidants and amino acids, they can provide nutritional assistance for optimal energy and healthy stress management.*	Vitamin A (50% as beta carotene and as retinyl acetate), Vitamin C (as ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E (as d-alpha tocopheryl acetate), Thiamin (as thiamin HCl) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Biotin, Pantothenic Acid (as calcium D-pantothenate), Calcium (as calcium lactate), Iodine (as potassium iodide), Magnesium (as magnesium glycinate), Zinc (as zinc sulfate), Selenium (as L-selenomethionine), Copper (as copper gluconate), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Potassium (from whey protein, guar gum, potassium citrate and potassium iodide), Whey Protein (milk), Malic Acid, Betaine, Inositol, Inulin (from chicory root), Hesperidin 50% (from citrus fruits), Taurine, Glycine, L-Tyrosine, N-Acetylcysteine (NAC), L-Serine, Stevia (Stevia rebaudiana) leaf Extract 15:1, Sweet Cherry (Prunus avium) Fruit Extract 10:1, Cranberry (Vaccinium macrocarpon) Fruit Extract 12:1, Bilberry (Vaccinium myrtillus) Fruit Extract 4:1, Boron (as sodium borate), Lutein (from Calendula officinalis), Zeaxanthin (from Calendula officinalis)



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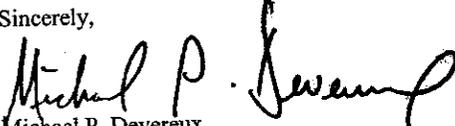
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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



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

November 8, 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

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PRODUCT NAME	STATEMENTS	INGREDIENTS TO WHICH THE CLAIM REFERS
Liquid Calcium Magnesium with Botanicals	<p>Provides synergistic bone-enhancing nutrients.*</p> <p>Bone health is built on calcium...and more!*</p> <p>Liquid Calcium Magnesium with Botanicals maintains optimum bone health* and may reduce the risk of osteoporosis.</p> <p>Vitamin D and boron promote the absorption of calcium.*</p> <p>Giving your bones what they need has never been easier...or more delicious!*</p> <p>Features a highly concentrated and bioavailable form of calcium plus magnesium.*</p>	<p>Vitamin D (as ergocalciferol), Calcium (as calcium carbonate), Magnesium (as magnesium oxide), Boron (as boron oxide)</p>

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: 11/8/06

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

#1811 Liquid Calcium Magnesium with Botanicals-Vanilla 2e



2006-8631



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