



FEB - 8 2007

150 7 0016 P-35

Mr. Gian T. Zisa
Manager, Regulatory Affairs - Nutritionals
Bayer Healthcare LLC
36 Columbia Road
PO Box 1910
Morristown, New Jersey 07962-1910

Dear Mr. Zisa:

This is in response to your letter of January 30, 2007 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)).

The product **Heart Vitality** is the subject of claims that represent that it contains phytosterols that will lower cholesterol and reduce the risk of heart disease. These statements are not claims subject to 21 U.S.C. 343(r)(6), but claims subject to 21 U.S.C. 343(r)(1)(B) because they represent that the product will reduce the risk of a disease or health related condition (i.e., coronary heart disease). FDA has authorized a health claim about the relationship between phytosterol and phytostanol esters and coronary heart disease (see 21 CFR 101.83)¹. A dietary supplement that meets the eligibility and message requirements set forth in the regulation may bear a claim for the relationship between phytosterol/stanol esters and coronary heart disease. 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 101.83 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 101.83 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, coronary heart disease.

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¹Also see February 14, 2003 letter regarding enforcement discretion with respect to expanded use of an interim health claim rule about plant sterol/stanol esters and reduced risk of coronary heart disease; <http://www.cfsan.fda.gov/~dms/ds-ltr30.html>.

Page 2 - Mr. Gian T. Zisa

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Vasilios H. Frankos". The signature is fluid and cursive, with a long horizontal stroke at the end.

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, New Jersey District Office, Office of Compliance, HFR-CE340

Bayer HealthCare
Consumer Care Division

1/31/07



January 30, 2007

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Gian T. Zisa, M.S.
Manager, Regulatory
Affairs- Nutritional

**Subject: 30-Day Post-Market Notification for Structure/Function Claims;
Bayer Nutritional Science™ Heart Vitality™
DIETARY SUPPLEMENT**

Bayer HealthCare LLC
Consumer Care Division
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910

Dear Sir or Madam:

Bayer Consumer Care Division submits the information in this notification pursuant to Section 403(r)(6) of the Food, Drug and Cosmetic Act as notice of marketing structure/function claims on the product label of Bayer Nutritional Science™ Heart Vitality™ Dietary Supplement.

Phone: (973) 408-8009
Fax: (973) 408-8121

PRODUCT NAME:	Bayer Nutritional Science™ Heart Vitality™ Dietary Supplement
NAME /ADDRESS OF DISTRIBUTOR:	Bayer HealthCare LLC Consumer Care Division 36 Columbia Road P. O. Box 1910 Morristown, New Jersey 07962-1910
NAME OF DIETARY INGREDIENT/ SUPPLEMENT (SUBJECT OF THE STATEMENT):	Bayer Nutritional Science™ Heart Vitality™ Dietary Supplement
TEXT OF STATEMENTS BEING MADE:	
Principal Display Panel (carton/label):	Keep Your Heart Strong & Healthy Significantly lowers bad (LDL) cholesterol levels‡ and helps maintain healthy blood pressure levels*†

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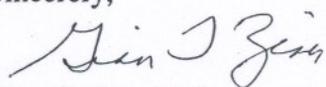
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<p>Right Panel of Carton:</p>	<p>Having healthy cholesterol and blood pressure levels are two key ways to keep your heart strong and healthy.</p> <p>New Bayer Nutritional Science™ Heart Vitality™ utilizes the latest science to help you address these two factors. It's specially formulated with scientifically proven levels of plant-based Phytosterols to significantly lower bad (LDL) and total cholesterol levels.‡ It also contains Folic Acid to help maintain healthy blood pressure levels*.†</p> <p>Heart Vitality™ is the only product** which provides the full amount of phytosterols (2 grams) recommended by The National Cholesterol Education Program (NCEP). Most people can expect to start seeing cholesterol-lowering results in 2-4 weeks.‡</p> <p>Keep Your Heart Strong & Healthy</p> <ul style="list-style-type: none"> - Plant-based Phytosterols, clinically shown to significantly lower bad (LDL) and total cholesterol levels by working with your body to block the absorption of bad cholesterol‡ - Folic Acid, to help maintain healthy blood pressure† by lowering homocysteine levels in the blood* - CoQ10, a heart-healthy antioxidant*
<p>*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.</p>	
<p>** Compared to leading brands. †For blood pressure levels already within the normal range ‡Dietary Supplements or foods containing at least 400 mg per serving of free phytosterols, eaten twice a day with meals for a daily total intake of at least 800 mg, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. The daily intake Heart Vitality (2 Tablets) supplies 2,000 mg of free phytosterols.</p>	

In accordance with 21 CFR 101.93, the information contained in this notification is complete and accurate. Bayer Consumer Care Division has substantiation on file that the statements are truthful and not misleading. This notification is comprised of an original and two (2) copies.

Should you have any questions or need any additional information, please contact the undersigned at (973) 408-8009 or William Walsh at (973) 408-8046.

Sincerely,



Gian T. Zisa, M.S.

Manager, Regulatory Affairs- Nutritionals

BAYER HEALTHCARE LLC, CONSUMER CARE DIVISION