



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

MAY - 9 2007

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Ms. Jacquelyn Alfonso
Product Development Manager
JOL Management
6701 Center Drive West, Suite 1500
Los Angeles, California 90045

Dear Ms. Alfonso:

This is in response to your letter of April 6, 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 Super Omega (Gero Vita) is using a claim about omega-3 fatty acids and a reduced risk of coronary heart disease. 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) because it represents that the product will reduce the risk of a disease or health related condition (i.e., coronary heart disease). FDA has issued letters defining the conditions in which it would exercise enforcement discretion with respect to the use of a qualified health claim for dietary supplements containing omega-3 fatty acids.¹ A dietary supplement that meets the eligibility and message requirements set forth in the enforcement discretion letters may bear a claim for the relationship between omega-3 fatty acids 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 the relevant enforcement discretion letters 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 the applicable enforcement discretion letters 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.

¹See letters regarding enforcement discretion with respect to use of qualified health claims about reduced risk of coronary heart disease;
<http://www.cfsan.fda.gov/~dms/lab-qhc.html>.

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Page 2 - Ms. Jacquelyn Alfonso

Please contact us if we may be of further assistance.

Sincerely yours,

for Robert J Moore

Vasilios H. Frankos, Ph.D.

Director

Division of Dietary Supplement Programs

Office of Nutrition, 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, Los Angeles District Office, Office of Compliance, HFR-PA240



April 6, 2007

Office of Nutritional Products
 Labeling and Dietary Supplements (HFS-800)
 Center for Food Safety and Applied Nutrition
 Food and Drug Administration
 5100 Paint Branch Parkway
 College Park, MD 20740-3835

Dear Sir or Madam:

In accordance with the requirements of section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act, this letter serves as notification that JOL Management, located at 6701 Center Drive West, Suite 1500, Los Angeles, CA 90045, is marketing the below listed dietary supplement(s) that bear statements of nutritional support on the labels and/or labeling.

Product	Brand	Statements
Enzymate	Gero Vita™	<p>Each capsule of Gero Vita™ Enzymate supplies all the basic digestive enzymes to support the proper digestion of food.</p> <p>Give Your Body Enzymes to Support Digestion Are you really getting the nutrients you need? Not if your body lacks the enzymes it needs to break down food and use it properly. That's where Enzymate comes in. Enzymes play a critical role in many natural processes in the body, including digestion. Without the right enzymes, your body would be unable to break down the foods you eat into absorbable components. Enzymate is a special blend of nine digestive enzymes that offers a full spectrum of support.</p> <p>Amylase - helps the body digest carbohydrates Invertase - assists with the breakdown of sugars Protease - facilitates protein digestion Lipase - helps break down fat Malt diastase - supports the digestion of starches And More!</p>

Florametric	Gero Vita™	<p>Each Florametric tablet supplies a specially formulated blend of probiotics to help maintain the natural balance of healthy microflora in the intestines and support healthy bowel function.</p> <p>Get the Power of Probiotics on Your Side! Your body needs probiotic bacteria like those found in Florametric for proper digestion. Stress, dietary deficiencies, and, most of all, age can all take their toll on your body's balance of natural intestinal flora.</p> <p>Florametric offers all the benefits of probiotic bacteria—without the sugar, fat, or hard-to-digest lactose found in other common sources such as yogurt.</p> <p>Florametric contains an array of beneficial pre- and probiotics to encourage normal digestion, soothe stomach discomforts, support normal bowel functions, help with lactose intolerance, and maintain normal intestinal flora.</p> <p>Included in our proprietary blend are potent probiotic strains of <i>Bifidobacterium bifidum, longum, and lactis</i>; <i>Lactobacillus acidophilus, rhamnosus, and casei</i>; and <i>Streptococcus thermophilus</i>, all known for their benefits to digestive health and overall balance.</p>
Super Omega	Gero Vita™	<p>Super Omega is a natural source of essential fatty acids and contains a highly concentrated blend of omega-3, omega-6, and omega-9 fatty acids drawn from high-quality perilla oil and fish oil.</p> <p>Get All of Your Omegas...in One Pill! If you want to fortify your heart and brain, nothing beats the power of the omega nutrients: <i>omega-3, omega-6, and omega-9</i>. They are essential fatty acids (EFAs) that your body needs to support healthy arteries and flexible blood vessels. But the human body doesn't produce its own EFAs. And chances are you're probably not getting enough from the food you eat.</p> <p>Many Americans have insufficient levels of EFAs, including the omega nutrients. That's why it's wise to take Super Omega, a fully balanced supplement that contains omega EFAs from rich, certified sources. Even better, Super Omega goes beyond other supplements by giving you <i>perilla oil</i>, the richest, most reliable source of omega EFAs. With this potent combination, Super Omega helps promote a healthy heart.</p> <p>With perilla oil Balanced ratio of EFAs Easy-to-digest softgel Contents: 180 Softgels</p>

		Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease.
Triple Omega 3-6-9	Gero Vita™	This formula provides a healthy ratio of omega-3, omega-6, and omega-9 fatty acids, the “good fats” that help support heart, brain, and cellular health. Each softgel contains a combination of flaxseed oil , fish oil and borage seed oil . Get all three essential fatty acids, plus the antioxidant vitamin E, in this convenient, easy-to-swallow softgel.

Where applicable the product label(s) and/or labeling contain the disclaimer “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.”

Please be informed that the information contained in this notification is complete and accurate and that JOL Management has substantiation that the statements are truthful and not misleading.

Sincerely,



Jacquelyn Alfonso
Product Development Manager