



DEC - 6 2004

James L. Wilmer, Ph.D.
Director, Scientific Affairs
Market America, Inc.
1302 Pleasant Ridge Road
Greensboro, North Carolina 27409

Dear Dr. Wilmer:

This is in response to your letters of October 27, 2004 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 letter states that the products **Essential Omega III** and **TriActive™** will use the claims “[H]elp maintain healthy...cholesterol...levels” and “[S]upport...healthy cholesterol levels,” respectively¹.

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Therefore, because the claims you are making for these products represent that the products are intended to affect blood cholesterol but do not also include a statement about them being intended to affect blood cholesterol that is already in the normal ranges, they are implied disease claims.

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 these products suggest that they are intended to treat, prevent, or mitigate disease. These claims do not

¹Although a qualified health claim for the relationship between omega-3 fatty acids and coronary heart may be used in the labeling of dietary supplements (see February 8, 2002 letter; <http://www.cfsan.fda.gov/~dms/ds-ltr28.html>) your claim for the product **Essential Omega III** does not appear to be intended to be such a claim. A qualified health claim is, however, not a claim under section 403(r)(6) of the Act.

975-0163

LET 800

Page 2 - Dr. James L. Wilmer

meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.

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, Atlanta District Office, Office of Compliance, HFR-SE140

RECEIVED
11/30/04

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **1302 Pleasant Ridge Road, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Essential Omega III**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "Essential Omega III Fish Oil with Vitamin E offers one of the highest amounts of beneficial fish oils, EPA and DHA to help maintain healthy triglyceride, cholesterol and C-reactive protein levels."—Booklet

Statement 2: "Heart Health - Cardiovascular Maintenance"—Bottle Label

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

<u>Statement Number(s)</u>	<u>Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement</u>
1.-2.	Essential Omega III is composed of the following ingredients: 100% natural vitamin E (d-alpha tocopherol), eicosapentaenoic omega-3 fatty acid, docosahexaenoic omega-3 fatty acid; other ingredients include: gelatin, glycerin, and natural lemon flavor.

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.-2.	Essential Omega III	Bottle Label and Booklet

90294

I, **James L. Wilmer**, am authorized to certify this Notification on behalf of **Market America, Inc.** I certify that the information presented and contained in this Notification is complete and accurate, and that **Market America, Inc.** has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: November 12, 2004

By: James L. Wilmer

James L. Wilmer, Ph. D.
Director, Scientific Affairs
Market America, Inc.

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR §101.93**

11/30/04

This notification is being filed on behalf of **Market America, Inc.** which is the **distributor** of the product bearing the statements identified in this notification. Its business address is **1302 Pleasant Ridge Road, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **TriActive™ – Arterial, Cholesterol & Homocysteine Support Formula**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "TriActive targets three major areas to promote the healthy performance of the body's cardiovascular system."—Booklet

Statement 2: "This unique formula uses a combination of natural ingredients that have been shown to safely and effectively support optimal arterial function, healthy cholesterol levels, and healthy homocysteine levels."—Booklet

Statement 3: "TriActive has been formulated using a combination of clinically proven ingredients that help support proper heart health." —Booklet

Statement 4: "To help maintain arterial integrity, TriActive contains garlic, a well-known cardio-protective supplement."—Booklet

Statement 5: "It not only promotes the optimal health of the arteries but it also helps maintain healthy homocysteine levels and healthy cholesterol levels."—Booklet

Statement 6: "It supports heart function by maintaining healthy blood flow."—Booklet

Statement 7: "TriActive targets three major areas to protect against damage and enhance the performance of the body's total cardiovascular system."— Website

Statement 8: "Arterial, Cholesterol, & Homocysteine Support Formula"—Bottle Label

Statement 9: "Heart Health - Cardiovascular Maintenance"—Bottle Label

90294

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

<u>Statement Number(s)</u>	<u>Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement</u>
----------------------------	--

1.-9.	TriActive is composed of the following ingredients: thiamin (vitamin B1 as thiamin mononitrate), riboflavin (vitamin B2), niacin (vitamin B3 as niacinamide), pantothenic Acid (vitamin B5 as calcium d-pantothenate), vitamin B6 (as pyridoxine hydrochloride), vitamin B12 (as cyanocobalamin), biotin, folate (as Metafolin [®]), zinc (as zinc oxide), garlic (<i>Allium sativum</i>), beta-sitosterol (from 637.5 mg 40% beta-sitosterol plant sterols), hawthorn berry, <i>Cassia nomame</i> (minimum 6% flavonoids), guggulsterones (from 95% guggulsterones granules); other ingredients include: dicalcium phosphate, cellulose, vegetable stearic acid, vegetable magnesium stearate, croscarmellose, silica and vegetable acetoglycerides.
-------	---

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.-9.	TriActive [™]	Bottle Label and Booklet

I, James L. Wilmer, am authorized to certify this Notification on behalf of Market America, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that Market America, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: October 27, 2004

By: James L. Wilmer

James L. Wilmer, Ph. D.
Director, Scientific Affairs
Market America, Inc.