



APR 17 2006

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

Dear Dr. Wilmer:

This is in response to your letter of March 29, 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)). Your submission states that Market America is marketing the product Awake™ as a dietary supplement.

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., "Awake provides a gradual energy boost without the caffeine "crash" of many other energy drinks," "[A]wake is the healthy alternative to other popular energy drinks," and "[I]s a healthy alternative to caffeinated beverages"). 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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Page 2 - Dr. James L. Wilmer

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a stylized flourish at the end.

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

1302 Pleasant Ridge Road
Greensboro, North Carolina 27409
Voice: 336.605.0040



FAX: 336.605.0041
E-Mail: mamerica@morebv.com
Web Site: marketamerica.com

March 29, 2006

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S. W.
Washington, D. C. 20204

APR 12 2006

HFS 810

Dear Sir/Madam:

I have enclosed notification forms that are intended to comply with Section 6 of the Dietary Supplement Health and Education Act of 1994 and Rule 21 C.F.R. §101.93. One dietary supplement called AWAKE™ is discussed. I have listed the structure-function statements found on the product label and associated support literature, and have identified the product ingredients that are the subject of the statements.

Thank you.

Sincerely,

A handwritten signature in cursive script that reads "James L. Wilmer".

James L. Wilmer, Ph. D.
Director, Scientific Affairs

Enclosures: 1 original and 2 copies

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06-3218

**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 **AWAKE™**.

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

Statement 1: "Awake provides a gradual energy boost without the caffeine "crash" of many other energy drinks."—Brochure

Statement 2: "Using a proprietary formula, Awake improves overall mental and physical endurance, helps support the body with antioxidants and offers cardiovascular support."—Brochure

Statement 3: "Packed with B-vitamins and selected amino acids for a steady, natural energy boost, Awake is the healthy alternative to other popular energy drinks."—Brochure

Statement 4: "AWAKE...endurance • energy • mental acuity"—Brochure

Statement 5: "It [AWAKE] provides a gradual energy boost with no caffeine "crash", improves overall endurance, supplies the body with an antioxidant & cardiovascular defense, and is a healthy alternative to caffeinated beverages."—Online

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

Statement Number(s)	Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement
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1.-5.	AWAKE™ is composed of the following ingredients: beta-carotene (vitamin A precursor), vitamin C (ascorbic acid), vitamin E (d-alpha-tocopherol acetate), vitamin B ₁ (thiamin hydrochloride), vitamin B ₂ (riboflavin), vitamin B ₃ (niacinamide), vitamin B ₆ (pyridoxine hydrochloride), folate, vitamin B ₁₂ (cyanocobalamin), vitamin B ₅ (pantothenic acid) (calcium pantothenate), iron (ferrous bis-glycinate), zinc (monomethionine), copper (gluconate), chromium
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(citrate), sodium (bicarbonate), potassium (bicarbonate), l-tyrosine, choline (bitartrate), glucuronolactone, taurine, l-carnitine, glycine; other ingredients include: maltodextrin, fructose, dextrose, citric acid, natural flavors, sucralose and silicon dioxide.

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

Statement Number(s)	Brand Name	Label or Labeling
1.-4.	AWAKE™	Brochure
5.	AWAKE™	Online

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: March 29, 2006

By: James L. Wilmer

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