



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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MAY 24 2005

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 letter of May 4, 2005 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, Inc. is making the following claims, among others, for the product **Glucosatin®**:

“[M]ay help control joint inflammation and assist in the regeneration of cartilage...control bone loss and joint pain.”

“[A]ssist you in pain-free movement

“[A]nti-inflammatory and help regenerate healthy cartilage....”

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 this product suggest that it is intended to prevent or treat disease because they imply that the product is intended to treat arthritis. Arthritis is defined as “Inflammation of a joint or a state characterized by inflammation of joints.” Stedman’s Medical Dictionary, 26th Edition. The claims for the product unambiguously describe its intended use to mitigate, treat and cure joint pain from inflammatory and/or degenerative joint conditions. Taken together, these claims evidence that the product is intended for use in the diagnosis, mitigation, treatment, cure, or prevention of a specific disease, namely, arthritis. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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 20852.

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Page 2 - Dr. James L. Wilmer

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

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

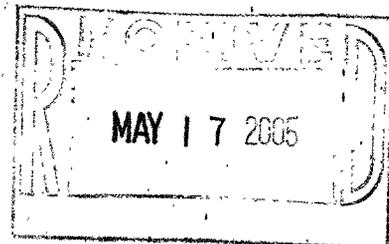


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FAX: 336.605.0041
E-Mail: mamerica@morebv.com
Web Site: marketamerica.com

May 4, 2005

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



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

MAY 17 2005

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 **Glucosatin®**.

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

Statement 1: "Market America's Glucosatin® formula contains several ingredients that may help control joint inflammation and assist in the regeneration of cartilage, as well as help maintain proper bone health so that you can control bone loss and joint pain."—Brochure

Statement 2: "With the daily use of Glucosatin, your joints may maintain their natural flexibility and assist you in pain-free movement."—Brochure

Statement 3: "Glucosatin contains various key ingredients, including vitamins, minerals and herbs, that promote healthy cartilage in the joints and help maintain appropriate levels of vitamins and minerals that control bone resorption." —Brochure

Statement 4: "Glucosatin is made from a powerful combination of ingredients that are anti-inflammatory and help regenerate healthy cartilage within the joints and collagen for bones." —Brochure

Statement 5: "Start on your way toward better bone and joint health today with Market America's Glucosatin formula." —Brochure

Statement 6: "A Nutritional Approach for Healthy Joints and Bones"—Brochure

Statement 7: "Glucosatin® helps relieve joint stiffness caused by overactivity and helps reduce overall wear and tear from growing old - or from being overweight."—Website

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>
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1-7.	Glucosatin is composed of the following ingredients: vitamin C (ascorbic acid), vitamin D3 (as cholecalciferol), zinc (as zinc sulfate), copper (as copper gluconate), manganese (as manganese sulfate), glucosamine HCl, <i>Scutellaria baicalensis</i> (Chinese skullcap) root, oleanolic acid, boswellia gum resin extract, hops strobile extract; other ingredients include: microcrystalline cellulose, stearic acid, croscarmellose sodium, magnesium stearate, silica, and pharmaceutical glaze.
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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>
1-6.	Glucosatin® *	Brochure and Bottle Label
7.	Glucosatin®	Website

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: May 5, 2005 By: James L. Wilmer

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