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SEP - 4 2007

Mr. Marc Ashley
Market America, Inc.
1302 Pleasant Ridge Road
Greensboro, North Carolina 27409

Dear Mr. Ashley:

This is in response to your letters received by the Food and Drug Administration (FDA) on August 23 and 30, 2007 pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your notice states that Market America, Inc. is making the claims "Helps maintain healthy cholesterol levels...", "[S]upports healthy blood pressure levels," "Promotes Healthy Glucose Levels," "Vitamin C may also have enhancing effects in regards to...allergies, blood pressure...", "Vitamin C aids in...wound healing and supports healthy cholesterol levels." "Calcium may also support healthy blood pressure and cholesterol," "Chromium...maintenance of healthy blood levels of cholesterol," "Vanadium supports healthy blood glucose levels," "Magnesium...help maintain normal blood pressure," and "Biotin helps maintain a steady blood sugar level" for the products Isotonix Acai, Isotonix Advanced B-Complex, and Isotonix Multi-Mineral.

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. The same principle applies to claims about blood pressure and blood glucose. Because the claims you are making for these products represent that the products are intended to affect blood cholesterol, blood glucose, and blood pressure but do not also include a statement about them being intended to affect blood cholesterol, blood glucose and blood pressure that are 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 diseases, including wound

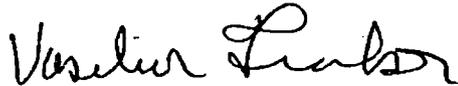
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Page 2 - Mr. Marc Ashley

healing and allergies. These claims do not 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,



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

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR 5101.93

AUG 30 2007

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 5101.93. The dietary supplement product on whose label or labeling the statements appear is Isotonix® Multi-Mineral.

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

Statement 1: "Isotonix® Multi-Mineral provides essential minerals that support healthy enzymatic and cellular functions in the body."—Online*

Statement 2: "Promotes a Healthy Heart / Promotes cardiovascular health"—Online*

Statement 3: "Promotes normal thyroid function"—Online*

Statement 4: "Essential for growth, development and overall immune function of the body"—Online*

Statement 5: "Promotes Skeletal Health"—Online*

Statement 6: "Supports Normal Muscle Use and Performance"—Online*

Statement 7: "Promotes Healthy Glucose Levels"—Online*

Statement 8: "Promotes Normal Functioning of the Immune System"—Online*

Statement 9: "It [Vitamin C] may also have enhancing effects in regards to the cardiovascular system, allergies, blood pressure, vision and respiratory functions."—Online*

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Statement 10: "It [Vitamin C] aids in the synthesis of collagen, wound healing and supports healthy cholesterol levels."—Online*

Statement 11: "Vitamin D works with calcium to increase bone strength and harden the bones."—Online*

Statement 12: "It [vitamin D] works to increase active transport of calcium out of the osteoblasts into the extra-cellular fluid and in the kidneys."—Online*

Statement 13: "It [vitamin D] helps skin cells grow normally."—Online*

Statement 14 "Apart from being a major constituent of bones and teeth, calcium is crucial for muscle contraction, nerve conduction, the beating of the heart, blood coagulation, glandular secretion, the production of energy and the maintenance of immune function."—Online*

Statement 15: "It [calcium] may also support healthy blood pressure and cholesterol."—Online*

Statement 16: "Calcium has been shown to reduce the symptoms of PMS in women."—Online*

Statement 17: "One preliminary study also suggests that calcium may assist in weight loss."—Online*

Statement 18: "Iron has been found to be helpful for increasing oxygen transport, thus improving exercise capacity, stimulating the immune system, increasing energy levels, and promoting neurotransmitter and collagen production."—Online*

Statement 19: "Magnesium helps indirectly in reversing the effects of oxidative stress and lipid peroxidation as involved with the aging process."—Online*

Statement 20: "Magnesium is required for energy release, regulation of the body temperature, proper nerve function, helping the body handle stress, and regulating metabolism."—Online*

increases libido, enhances the effect of fluorine in tooth decay prevention, and inducing sleep.”—Online*

Statement 31: “Sodium bicarbonate also improves endurance performance.”—Online*

Statement 32: “Among other things, it [potassium] is important in the transmission of nerve impulses, the contraction of cardiac, skeletal and smooth muscle, the production of energy, the synthesis of nucleic acids, the maintenance of intracellular tonicity and the maintenance of normal blood pressure.”—Online*

Statement 33: “Potassium also regulates water balance and assists recuperative powers. Potassium is crucial for the elimination of wastes.”—Online*

Statement 34: “Studies have shown that vanadium supports healthy blood glucose levels.”—Online*

Statement 35: “Boron helps to build and maintain healthy bones.”—Online*

Statement 36: “It [boron] helps retain adequate amounts of calcium and magnesium to prevent bone demineralization.”—Online*

Statement 37: “It [boron] enhances the maintenance of healthy cell membranes, proper mental functioning and alertness.”—Online*

Statement 38: “It [boron] elevates serum estrogen levels and ionized calcium.”—Online*

Statement 39: “Provides 14 essential minerals that support the metabolic process and regulation of water and electrolyte balance, and promote a sound skeleton, regulation of functions of muscles and nerves, and regulation of hormonal activities.”
- Online

Statement 40: It [chromium] may contribute to an increase in lean body and muscle mass. - online*

Statement 41: Potassium promotes normal muscle relaxation and insulin release. It also promotes glycogen and protein synthesis. Potassium is an electrolyte that promotes proper heartbeat. Potassium is important in releasing energy from protein, fat and carbohydrates during metabolism. - Online*

- * www.marketamerica.com
- * www.marketamericascience.com

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

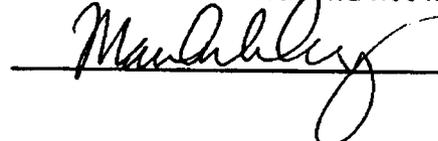
<u>Statement Number(s)</u>	<u>Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement</u>
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1.-38.	Isotonix [®] Multi-Mineral is composed of the following ingredients: beta-carotene, vitamin C (ascorbic acid), vitamin D3 (cholecalciferol), calcium (lactate), iron (gluconate), iodine (potassium iodide), magnesium (carbonate), zinc (gluconate), selenium (L-selenomethionine), copper (gluconate), chromium (nicotinate), molybdenum (sodium molybdate), sodium (bicarbonate), potassium (bicarbonate), boron (sodium borate), vanadium (sulfate); other ingredients include: fructose, orange fruit powder, citric acid, orange flavor, malic acid, passion fruit flavor, beta-carotene, lo han fruit extract, tartaric acid.
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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.-38.	Isotonix [®] Multi-Mineral	Website

I, Marc Ashley, 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: Aug 8, 2007 By: 

Marc Ashley, Chief Operating Officer
Market America, Inc.

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

AUG 30 2007

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 Isotonix® Advanced B-Complex.

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

Statement 1: "Supports cardiovascular health."—Online*

Statement 2: "Increases energy, stamina and endurance."—Online*

Statement 3: "Helps maintain healthy serotonin levels." —Online*

Statement 4: "Promotes normal cognitive performance" —Online*

Statement 5: "Promotes healthy levels of homocysteine and supports normal endothelial function" —Online*

Statement 6: "Helps decrease stress and improve mood"—Online*

Statement 7: "It [Vitamin B12] assists with concentration and promotes mental clarity"—Online*

Statement 8: "It [Vitamin B2] promotes healthy red blood cell formation, supports the nervous system, respiration, antibody production and general human health."—Online*

Statement 9: "It [Vitamin B2] helps maintain normal thyroid activity."—Online*

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Statement 10: "Vitamin B6 is involved in the synthesis of neurotransmitters in brain and peripheral nerve cells, it has been recommended as a nutrient to enhance mental function, specifically mood, and it supports nerve conduction."—Online*

Statement 11: "Magnesium has been shown to help keep the heart strong and help maintain normal blood pressure."—Online*

Statement 12: "Among other things, potassium is important in the transmission of nerve impulses, the contraction of cardiac, skeletal and smooth muscle, the production of energy, the synthesis of nucleic acids, the maintenance of intracellular tonicity and the maintenance of normal blood pressure."—Online*

Statement 13: "It [vitamin B2] supports healthy skin, nails and hair growth." - Online*

Statement 14: "Under some conditions, vitamin B2 can act as an antioxidant." - Online*

Statement 15: "Magnesium helps slow the aging process by combating oxidative stress and lipid peroxidation." - Online*

Statement 16: "Pantothenic acid aids in proper neurotransmitter activity in the brain, detoxifies brain tissue, relieves physical and emotional stress and plays very important role in the secretion of hormones." - Online*

Statement 17: "Biotin helps maintain a steady blood sugar level." - Online

Statement 18: "Vitamin B-12 promotes normal DNA and RNA synthesis." - Online*

* www.marketamerica.com

* www.marketamericascience.com

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.-18. Isotonix® Advanced B-Complex is composed of the following ingredients: thiamin HCl (vitamin B1), riboflavin 5-phosphate (vitamin B2), niacinamide (vitamin B3), vitamin B6 (pyridoxine HCl), folate (folic acid), vitamin B12 (cyanocobalamin), biotin, D-calcium pantothenate (vitamin B5), magnesium (carbonate), potassium (bicarbonate); other ingredients include: fructose, glucose, citric acid, maltodextrin, silica, pectin, calcium sulfate and natural lemon-lime 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.-18.	Isotonix® Advanced B-Complex	Website

I, **To be Determined**, 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: August 8, 2007 By: Marc Ashley

Marc Ashley, Chief Operating Officer
Market America, Inc.

RECEIVED
8/23/07

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND RULE 21 CFR 5101.93

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 5101.93. The dietary supplement product on whose label or labeling the statements appear is Isotonix® Acai.

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

Statement 1: "The power of the new Acai supports cardiovascular health and helps you maintain a healthy weight."—Online*

Statement 2: "Increases energy & provides antioxidant support."—Online*

Statement 3: "The proprietary blend of Isotonix Açai works to increase energy, supports immune functions, promotes cognitive health and supports weight control."—Online*

Statement 4: "Supports normal cell cycle and cell integrity." —Online*

Statement 5: "Helps maintain healthy cholesterol levels." —Online*

Statement 6: "Helps improve mental focus and memory."—Online*

Statement 7: "Promotes healthy blood sugar levels."—Online*

Statement 8: "Supports weight control." - Online*

Statement 9: "Promotes prostate health."—Online*

137

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Statement 23: "L-phenylalanine suppresses appetite by fighting the sugar crash that commonly follows a binge on sugar or coffee." - Online*

Statement 24: " L-Taurine supports healthy blood pressure levels." - Online*

Statement 25: "Green tea helps to maintain normal triglyceride levels, promotes normal blood clotting and may aid in promoting thermogenesis." - Online*

Statement 26: "Copper promotes normal infant development, red and white blood cell maturation, iron transport, bone strength, cholesterol metabolism, myocardial contractility, glucose metabolism, brain development and immune function." - Online*

*www.marketamerica.com

*www.marketamericascience.com

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

Statement **Identity of Dietary Ingredient or Supplement**
Number(s) **That Is the Subject of the Statement**

1.-26. Isotonix® Acai is composed of the following ingredients: vitamin C (ascorbic acid, niacinamide, vitamin B6 (pyridoxine HCl), folic acid, vitamin B12 (cyanocobalamin), vitamin B5 (d-calcium pantothenate), zinc (gluconate), copper (gluconate), potassium (bicarbonate), açai fruit pulp, guarana extract, açai extract, mangosteen powder, pomegranate extract (40% ellagic acid), yerba maté extract, green tea extract (decaffeinated), L-phenylalanine, L- taurine, L-tyrosine, L-glycine; other ingredients include raspberry/grape flavor, maltodextrin, citric acid, fructose, and silicon dioxide.

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

<u>Statement</u> <u>Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1-26.	Isotonix® Acai	Website

I, Marc Ashley, 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: August 13, 2007

By: Marc Ashley
Marc Ashley, Chief Operating Officer
Market America