



SEP - 9 1998

6102 '98 SEP 11 P1:54

James L. Wilmer, Ph.D.  
Senior Science Officer  
Market America, Inc.  
7605 Business Park Drive  
Greensboro, North Carolina 27409

Dear Dr. Wilmer:

This is in response to your letter of August 31, 1998 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 products:

**Oxygen Plus**

“Bolsters the body’s own defenses against diseases...”

**Isotonix B-12 Special Formula**

“B12 helps reduce the effects of....depression...”

**Isotonix Vitamin C Formula**

“Vitamin C protects against infectious disease, including the common cold and influenza...”

“Vitamin C protects against hypersensitivity (exaggerated responses to allergenic substances) and periodontal disease”

**Isotonix Calcium Plus Formula**

“...calcium prevents many degenerative physical conditions...”

**Isotonix OPC-3 (Oligomeric proanthocyanidins)**

“As a homeopathic substance, OPC-3 is anti-inflammatory and anti-histaminic as an H3 enzyme blocker”

“It [OPC-3] acts against gum bleeding (loose teeth)...”

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

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products suggest that they are intended to prevent, treat or mitigate disease, namely depression, the common cold and flu, allergies, periodontal and other dental diseases, and degenerative bone conditions. The product **Isotonix OPC-3 (Oligomeric proanthocyanidins)** is represented "as a homeopathic substance." 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, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also indicates that you are making a claim of a relationship between calcium and osteoporosis for the product **Isotonix Calcium Plus Formula**. This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but is a claim subject to section 21 U.S.C. 343(r)(1)(B) for which FDA has authorized a health claim under 21 U.S.C. 343(r)(5)(D) (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. 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 21 CFR 101.72 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 21 CFR 101.72 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, osteoporosis.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Atlanta District Office, Office of Compliance, HFR-SE140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f, OSN#61007)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:9/4/98

init:GCF-1:DDorsey:9/4/98

f/t:HFS-456:rjm:9/8/98:docname:61007.adv:disc31



August 31, 1998

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 which 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. Thirteen health and nutrition products are discussed and presented on separate forms. As such, I have listed the structure-function statements found on product labels and associated support literature, identified the dietary ingredient or supplement that is the subject of the statement, and identified the brand name of each supplement for which a statement is made.

Thank you.

Sincerely,

*James L. Wilmer*  
James L. Wilmer, Ph. D.  
Senior Science Officer

Enclosures: 1 original and 2 copies



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

9/3/98

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 **7605 Business Park Drive, 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 **Oxygen Plus**.

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

**Statement 1:** "When used in accordance with the directions, Oxygen Plus antioxidants help to protect from the effects of free radical damage caused by exposure to sunlight, X-rays, ozone, tobacco smoke, car exhaust and other environmental pollutants."—bottle label.

**Statement 2:** "The natural antioxidant, anti-aging breakthrough."—brochure.

**Statement 3:** "Bolsters the body's own defenses against diseases associated with free radical damage from environmental pollutants, stress and the sun's ultraviolet rays."—brochure.

**Statement 4.** "Oxygen Plus™ is serious nutrition with a solid scientific foundation that bolsters the body's defenses against the ravages of time.

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

<b>Statement Number(s)</b>	<b>Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement</b>
1.—4.	Oxygen Plus™ is composed of the following ingredients: vitamin C (ascorbate), vitamin A ( <i>beta</i> -carotene precursor), vitamin E ( <i>d-alpha</i> -tocopherol succinate), green tea extract, <i>Ginkgo biloba</i> extract, milk thistle ( <i>Maria</i> ), glutathione, selenium, bilberry

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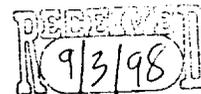
The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number(s)</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.	Oxygen Plus	bottle label
2.—4.	Oxygen Plus	brochure

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: August 31, 1998 By: James L. Wilmer  
James L. Wilmer, Ph. D.  
Senior Science Officer

**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 **7605 Business Park Drive, 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 B-12 Special Formula**.

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

**Statement 1:** "B12 helps reduce the effects of stress and depression, helps prevent 'tired blood' (anemia), and provides extra energy."—brochure.

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.	Isotonix B12 Special Formula is composed of the following ingredients: vitamin B-12 (cobalamin), folic acid, magnesium carbonate, potassium bicarbonate; base ingredients include fructose, dextrose, citric acid, maltodextrin, silica, calcium sulfate, fruit pectin, 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.	Isotonix B12 Special Formula	brochure

*Also see docket 975-0163*

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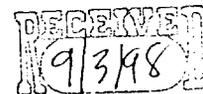
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By: James L. Wilmer

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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 **7605 Business Park Drive, 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 Vitamin C Formula**.

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

**Statement 1:** "Vitamin C protects against infectious disease, including the common cold and influenza, by strengthening the immune system."—brochure.

**Statement 2:** "It [vitamin C] also is a helper in the synthesis of collagen, which strengthens the cardiovascular system."—brochure.

**Statement 3:** "Vitamin C protects against hypersensitivity (exaggerated responses to allergenic substances) and periodontal disease."—brochure.

**Statement 4.** "Through its powerful antioxidant property, vitamin C promotes a vitamin-sparing effect, particularly with vitamin E and folic acid."—brochure.

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.—4.	vitamin C (ascorbic acid)

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.—4.	Isotonix Vitamin C Formula	brochure

Also see docket 975-0163

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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 **7605 Business Park Drive, 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 Calcium Plus Formula**.

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

**Statement 1:** "In coordination with vitamin D, calcium prevents many degenerative physical conditions including osteoporosis."—brochure.

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.	Isotonix Calcium Plus Formula is composed of the following ingredients: calcium gluconate, calcium chloride, calcium lactate, magnesium bicarbonate, potassium bicarbonate, boron amino acid chelate, vitamin D3; the base ingredients include: fructose, glucose, vitamin A (as <i>beta</i> -carotene precursor), maltodextrin, malic acid, citric acid, calcium sulfate, fruit pectin, silica, 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.	Isotonix Calcium Plus Formula	brochure

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By: James L. Wilmer  
James L. Wilmer, Ph. D.  
Senior Science Officer

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

RECEIVED  
9/3/98

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 **7605 Business Park Drive, 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 OPC-3 (Oligomeric Proanthocyanidins)**.

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

**Statement 1:** "These bioflavonoids have numerous functions in the body that include, but are not limited to, being powerful antioxidants crucial in supporting the circulatory system."—brochure.

**Statement 2:** "They strengthen the capillaries and enhance vitamin C and vitamin E functions."—brochure.

**Statement 3:** "Most importantly, OPC-3 is a super-effective free radical neutralizer."—brochure.

**Statement 4:** "In addition, red wine extract contains high levels of other polyphenols that are beneficial in counteracting free radical damage."—information handout glossy.

**Statement 5:** "As a homeopathic substance, OPC-3 is anti-inflammatory and anti-histaminic as an H3 enzyme blocker."—information handout glossy.

**Statement 6:** "It [OPC-3] acts against gum bleeding (loose teeth), protects the liver from lipid oxidation during excessive alcohol intake, protects against ionizing radiation (including x-rays and U. V. B.), and protects other essential biological functions."—information handout glossy.

**Statement 7:** "As a food supplement, OPC-3 protects unsaturated fats (the lipid constituents of cell membranes), particularly the lipids found in the retina of the eye and brain cells."—information handout glossy.

**Statement 8:** "It [OPC-3] is recommended in hypocaloric diets in which the few remaining unsaturated fats come under heavy attack from free radicals."—information handout glossy.

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**Statement 9:** "As a cosmetic, OPC-3 protects the skin against early aging and free oxygen radicals produced by U. V. radiation."—information handout glossy.

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.	Isotonix OPC-3 is composed of the following ingredients: grape seed extract, red wine extract, pine bark extract, bilberry extract, citrus extracts; the base ingredients include: fructose, glucose, maltodextrin, citric acid, calcium sulfate, apple pectin, silica, potassium bicarbonate.

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.—3.	Isotonix OPC-3	brochure
4.—9.	Isotonix OPC-3	information handout glossy

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