



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

0020 7 OCT -2 P12 .42

SEP 28 2007

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

Dear Mr. Ashley:

This is in response to your letter of September 6, 2007 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 notice states that Market America, Inc. is making the claim "Helps maintain healthy cholesterol...levels for the product Prime Hearing.

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. Because the claim you are making for this product represents that the product is intended to affect blood cholesterol but does not also include a statement about it being intended to affect blood cholesterol that is already in the normal ranges, it is an implied disease claim.

Your notice also states that the product Prime Hearing is the subject of the claims "May help to reduce mild tinnitus (ringing in ears)" and "[R]educe the severity of symptoms of mild tinnitus...."

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 treat, prevent, or mitigate diseases. 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 your client intends to make claims of this nature, they 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.

19775-0163

LET 961

Page 2 - Mr. Marc Ashley

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink that reads "Vasilios Frankos". The signature is written in a cursive style with a large, decorative initial "V".

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

MARKET AMERICA, INC.



September 6, 2007

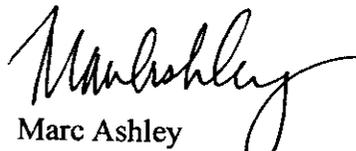
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S. W.
Washington, D. C. 20204

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 *Prime™ Hearing* 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,


Marc Ashley
Chief Operating Officer

Enclosures: 1 original and 2 copies

1302 PLEASANT RIDGE ROAD, GREENSBORO, NC 27409
PHONE: (336) 605-0040 FAX: (336) 605-0162

954

07-6698

**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 Prime™ Hearing: Tinnitus and Ear Health Formula.

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

Statement 1: "Helps to maintain hearing nerve health and functions"—Online*

Statement 2: "Helps to maintain the health of auditory cells exposed to noise"—Online*

Statement 3: "May help to clarify auditory sounds/noises" —Online*

Statement 4: "May help to maintain hearing as we age" —Online*

Statement 5: "May help to reduce mild tinnitus (ringing in ears)" —Online*

Statement 6: "Promotes circulation of blood, oxygen and nutrients to cells to promote optimal hearing"—Online*

Statement 7: "Promotes the health and retention of auditory cells"—Online*

Statement 8: "Prime Hearing promotes ear health by providing antioxidant protection for lipids, promoting normal blood flow to the inner ear and brain, helping to maintain healthy homocysteine levels, vasodilation and supporting normal nerve impulse transmissions." - Online*

Statement 9: "Green tea extract reportedly helps maintain healthy cholesterol and triglyceride levels and promotes normal blood clotting."—Online*

Statement 10: "Green tea contains a substantial amount of antioxidants which help to promote a healthy immune system."—Online*

Statement 11: "Green tea's polyphenolic antioxidants support cardiovascular health, reduce free radical oxidative damage to cells and support the normal oxidation of LDL cholesterol."—Online*

Statement 12: "Green tea reinforces the activities of antioxidant enzymes such as manganese superoxide dismutase (MnSOD), thereby reducing oxidative damage." - Online

Statement 14: "Vinpocetine promotes glucose and oxygen consumption by the brain." - Online

Statement 15: "Vinpocetine promotes normal dilation of arteries and capillaries in the head area, supporting healthy vascular resistance, promoting healthy production of ATP, and promoting healthy circulation to the brain and cells of the inner ear.— Online*

Statement 16: "Folic acid/folinic assists in the normal utilization of amino acids and proteins as well as constructs the material for DNA and RNA synthesis, this works toward supporting healthy cardiovascular and nervous systems."—Online*

Statement 17: "Magnesium promotes normal energy production, ion movements across cell membranes, heart and nerve function, retention of electrolyte balance and mental function."—Online

Statement 18: "Zinc supplementation has been proven to reduce the severity of symptoms of mild tinnitus and a decline in ear function.- Online

[*www.marketamerica.com](http://www.marketamerica.com)

[*www.marketamericascience.com](http://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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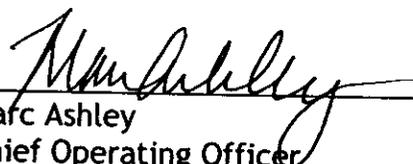
1.-18.	Prime™ Hearing is composed of the following ingredients: folic acid, magnesium (magnesium citrate), zinc (zinc gluconate), green tea extract (80% polyphenolic extract with 50% EGCG)(decaffeinated), vinpocetine (BioVinca®); other ingredients include microcrystalline cellulose, croscarmellose sodium, stearic acid, silicon dioxide and magnesium stearate.
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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>
1-18.	Prime™ Hearing	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: Sept 6, 2007

By: 
Marc Ashley
Chief Operating Officer
Market America