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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 letters of May 22 and 25, 2001 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 following products:

Isotonix Calcium Plus Formula

- "...maintaining proper blood pressure levels"
- "...inhibits the formation and growth of calcium oxalate stones in the kidney and bladder"

Isotonix Digestive Enzyme Formula

- "...help to...displace pathogenic bacteria"

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 a disease, namely hypertension, kidney stones, or gastrointestinal disorders caused by pathogens. 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.

You also stated that the labeling for this product will bear the statements "Many physicians recommend calcium supplements in an effort to prevent osteoporosis" and "Calcium supplementation is effective in decreasing the normal bone loss during aging and helping retard osteoporosis." These statements are claims of a relationship between calcium and osteoporosis. These statements are not claims subject to 21 U.S.C. 343(r)(6), but claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health

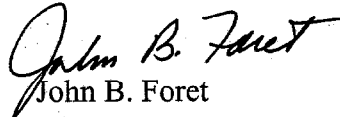
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claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. 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 you require further assistance.

Sincerely,



John B. Foret

Director
Division of Compliance and Enforcement
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-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Atlanta District Compliance, HFR-SE140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810 (Foret)

HFS-811 (file)

HFD-310

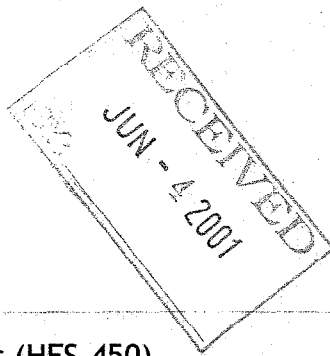
HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:6/5/1:docname:76116.adv:disc56



May 25, 2001

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

7 6206

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. One dietary supplement called *Isotonix Digestive Enzyme Formula with Probiotics* is discussed. I have listed the structure-function statements found on product labels and associated support literature, and have identified the product ingredients that are the subject of the statements.

Thank you.

Sincerely,

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

Enclosures: 1 original and 2 copies



**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 **Isotonix® Digestive Enzyme Formula with Probiotics**.

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

Statement 1: "An advanced system digestive aid."—Carton and bottle labels

Statement 2: "In addition, a special strain of bacteria, *Lactobacillus sporogenes*, has been added to the Formula and can inhabit the intestine, especially the colon, and degrade nutrients or toxins that are not absorbed."—Carton label

Statement 3: "These 'friendly' bacteria help to repopulate the colon and displace pathogenic bacteria as well as create an appropriate pH balance."—Carton label and brochure

Statement 4: "Probiotics can help support the body in maintaining proper digestive functions and improving emotional health."—Brochure

Statement 5: "Lactobacillus bacteria may also help neutralize food-borne toxins released during the digestive process."—Brochure

Statement 6: "Isotonix® Digestive Enzyme Formula with Probiotics helps your body replenish all the essential enzymes and 'good' bacteria necessary for maximum absorption of nutrients from the foods we eat."—Brochure

Statement 7: "Isotonix® Digestive Enzyme Formula with Probiotics acts to supplement and maximize the activity of the body's own enzymes and the 'friendly' bacteria our bodies need in an easy-to-take, pleasant-tasting drink."—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.-7. | Isotonix [®] Digestive Enzyme Formula with Probiotics is composed of the following ingredients: DigeZyme [®] (amylase, protease, cellulase, lactase, lipase), maltase, sucrase, magnesium carbonate, potassium bicarbonate, Lactospore [®] (<i>Lactobacillus sporogenes</i>); other ingredients include: fructose, glucose, citric acid, maltodextrin, silica, apple pectin, natural lemon-lime flavor, and calcium sulfate. |
|-------|---|

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.-7. | Isotonix [®] Digestive Enzyme Formula with Probiotics | Brochure, Bottle label, Carton label |

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 25, 2001

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

rec'd
5/30/01

**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 **Isotonix Calcium Plus Formula**.

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

Statement 1: "Studies indicate that calcium supplements could reduce the symptoms of pre-menstrual syndrome (PMS) by nearly half."—Brochure

Statement 2: "It [Calcium] has been proven beneficial in maintaining proper blood pressure levels."—Brochure

Statement 3: "Many physicians recommend calcium supplements in an effort to prevent osteoporosis."—Brochure

Statement 4: "Calcium supplementation is effective in decreasing the normal bone loss during aging and helping retard osteoporosis."—Brochure

Statement 5: "Magnesium inhibits the formation and growth of calcium oxalate stones in the kidney and bladder."—Brochure

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 |
|----------------------------|--|
|----------------------------|--|

| | |
|--------------|---|
| 1.-5. | Isotonix Calcium Plus Formula is composed of the following ingredients: calcium carbonate, calcium lactate, calcium phosphate, calcium sulfate, calcium citrate, magnesium oxide, magnesium carbonate, manganese sulfate, potassium bicarbonate, potassium citrate, sodium borate (boron), vitamin B ₂ (riboflavin-5-phosphate); vitamin C (ascorbic acid), vitamin D ₃ (cholecalciferol); other ingredients include: fructose, glucose, orange powder, citric acid, apple pectin, malic acid, and natural orange 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 |

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 22, 2001

By: James L. Wilmer

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