

Rec'd 5/25/01

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
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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.
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Also see docket 97S-0163

97S 0162

LET 8069

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.