



Monday, August 23, 2004

Ortho Molecular Products Inc
3017 Business Park Drive
PO Box 1060
Stevens Point, WI 54481
715 342 9881 Phone
800 332 2351
715 342 9866 Fax
orthomolecularproducts.com

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

RECEIVED
8/27/04

Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached label).

Name of Manufacturer: Ortho Molecular Products, Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481

Statement Text: OsteoPrev

Dietary Ingredients: Vitamin D3 (as Cholecalciferol), Vitamin K (as Phytanadione), Folic Acid, Calcium (as Hydroxyapatite, Citrimal), Phosphorus (as Chelate), Magnesium (as Buffered Amino Acid Chelate, Citrate), Selenium (as Amino Acid Complex), Copper (as Lysinate), Manganese (as Chelazome), Molybdenum (as Amino Acid Chelate), Ipriflavone, Strontium Citrate, Montmorillonite, Boron (as Proteinate), Turmeric Root Extract, Ascorbyl Palmitate, Microcrystalline Cellulose, and Silicon Dioxide.
Dietary Supplement Name: OsteoPrev

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Deborah Zurawski 8-23-04

Deborah Zurawski
Quality Assurance Manager
Ortho Molecular Products

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Suggested Use: As a dietary supplement, 4 capsules per day or as recommended by your health care professional.
Formulated to be free of the following: Gluten, corn, egg, dairy, peanuts, yeast, artificial colors and flavors.
If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. Keep container tightly closed. Store at room temperature. Keep out of reach of children.
Chelazome® and Citrimal® are registered trademarks of Albion, Inc. This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal is missing or damaged.
†This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Label ID: L OMP100-567120-A



Also Excellent for



Dietary Supplement Product #567



OsteoPrev

Supplement Facts	
Serving Size 4 Capsules	Amount Per Serving
Servings Per Container 30	% Daily Value
4 capsules contain	
Vitamin D3 (as Cholecalciferol)	1000 IU 250%
Vitamin K (as Phytanadione)	1 mg 1250%
Folic Acid	800 mcg 200%
Calcium	200 mg 20%
(as Hydroxyapatite, Citrimal®)	
Phosphorus (as Chelate)	15 mg 2%
Magnesium (as Buffered Amino Acid Chelate, Citrate)	150 mg 38%
Selenium	200 mcg 286%
(as Amino Acid Complex)	
Copper (as Lysinate)	1 mg 50%
Manganese (as Chelazome®)	10 mg 500%
Molybdenum (as Amino Acid Chelate)	150 mcg 200%
Ipriflavone	600 mg *
Strontium Citrate	200 mg *
Montmorillonite	150 mg *
Boron (as Proteinate)	5 mg *

Other Ingredients: Natural vegetable capsules and Turmeric Root Extract. This product may contain one or more of the following: Ascorbyl Palmitate, Microcrystalline Cellulose and Silicon Dioxide.

Mfg by Ortho Molecular Products, Inc. 3017 Business Park Drive, Stevens Point, WI 54481

OrthoMolecularProducts.com

120 Capsules