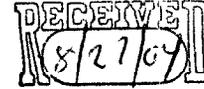


Monday, August 23, 2004

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



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 on page 2).

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

**Statement Text:** Pro Bono Premium Bone Building Pack

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

**Dietary Supplement Name:** Pro Bono

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

97S 0162 LET 14670



Attachment of Pro Bono Label

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

Suggested Use As a dietary supplement, 2 packets per day taking one Clear / White pack-
et in the AM and one Clear / Clear packet in the PM. Maintenance: 1 packet per day alter-
nating 1 Clear / White packet on odd days and 1 Clear / Clear packet on even days or as
recommended by your health care professional.

Formulated to be free of the following. Gluten, corn, egg, dairy, peanuts, 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.

Label ID L-OMP100-350060-B



Pro B
Premium Bone



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

Dietary Supplement
Product #350

Contents: 60 Packets

Also Excellent for:



OCULAR  
 PRODUCTS  
 Matters™

**ono™**  
**Building Pack†**

<b>Supplement Facts</b>		
Serving Size 2 Packets		
Servings Per Container: 30		
	Amount Per Serving	% Daily Value
2 packets contain		
Vitamin D3	1000 IU	250%
(as Cholecalciferol)		
Vitamin K	1 mg	1250%
(as Phylloquinone)		
Folic Acid	800 mcg	200%
Calcium	1000 mg**	100%
(as Hydroxyapatite, CitriMal®)		
Phosphorus	15 mg	1%
(as Chelate)		
Magnesium	400 mg	100%
(as Buffered Amino Acid Chelate, Citrate, Aspartate)		
Selenium	200 mcg	286%
(as Amino Acid Complex)		
Copper (as Lysinate)	1 mg	50%
Manganese	10 mg	500%
(as Chelazome®)		
Molybdenum	150 mcg	200%
(as Amino Acid Chelate)		
Ipriflavone	600 mg	*
Strontium Citrate	1000 mg***	*
Montmorillonite	150 mg	*
Boron (as Proteinate)	5 mg	*

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

†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.

This product was sealed for your protection. Do not use if outer logoed neck seal or printed inner seal are missing or damaged.