



May 17, 2005

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Ortho Molecular Products Inc.  
3017 Business Park Drive  
P.O. 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

MAY 25 2005

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 labels on page 2).

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

**Statement Text:** Muscular / Skeletal Health

**Dietary Ingredients:** Vitamin C (as Ascorbic Acid USP), Turmeric Root Extract (Standardized to contain 95% Curcumin), Bromelain (2400 GDU/g), Quercetin, Rutin, Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

**Dietary Supplement Name:** Traumeric

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,

Melissa Slager  
Document Control / Training Manager  
Ortho Molecular Products

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**Attachment of Traumeric Labels**

**Suggested Use:** As a dietary supplement, 2 or more capsules per day or as recommended by your health care professional.  
**Formulated to be free of allergens derived from:** Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. This product contains the following potential allergen: Pineapple / Bromelain. 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.**  
 † These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



Supplement Facts		
Serving Size 1 Capsule		
Servings Per Container: 30		
1 capsule contains	Amount Per Serving	% Daily Value
Vitamin C (as Ascorbic Acid USP™)	15 mg	25%
Turmeric Root Extract (Standardized to contain 95% Curcumin)	330 mg	*
Bromelain (2400 GDU/g)	120 mg	*
Quercetin	120 mg	*
Rutin	25 mg	*

\* % Daily Value not established

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

Label ID L-OMP100-551030-C  
 6 15033 00551 1  
 OrthoMolecularProducts.com Dietary Supplement Product #51 30 Capsules

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

**Suggested Use:** As a dietary supplement, 2 or more capsules per day or as recommended by your health care professional.  
**Formulated to be free of allergens derived from:** Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. This product contains the following potential allergen: Pineapple / Bromelain.  
 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.**  
 † These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



Supplement Facts		
Serving Size 1 Capsule		
Servings Per Container: 90		
1 capsule contains	Amount Per Serving	% Daily Value
Vitamin C (as Ascorbic Acid USP™)	15 mg	25%
Turmeric Root Extract (Standardized to contain 95% Curcumin)	330 mg	*
Bromelain (2400 GDU/g)	120 mg	*
Quercetin	120 mg	*
Rutin	25 mg	*

\* % Daily Value not established

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

Label ID L-OMP100-551090-C  
 6 15033 01551 0  
 OrthoMolecularProducts.com Dietary Supplement Product #551A 90 Capsules

This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.  
 Mfg. by Ortho Molecular Products Inc. 3017 Business Park Drive, Stevens Point, WI 54481  
 OrthoMolecularProducts.com