



February 18, 2005

Ortho Molecular Products Inc
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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

FEB 23 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.

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 Ascorbate), Magnesium (as Ascorbate), Manganese (as Chelazome), Potassium (as Ascorbate), Methylsulfonylmethane, L-Arginine USP, L-Proline USP, L-Cysteine HCl Monohydrate USP, Gotu Kola (Aerial Portion) Extract 4:1, Horsetail Grass (Aerial Portion), Activin (Grape Seed Extract), Centella Asiatica Purified Triterpenes, Natural Vegetable Capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, & Silicon Dioxide.

Dietary Supplement Name: Prolo Max

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
Quality Assurance Manager
Ortho Molecular Products

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Suggested Use: As a dietary supplement, 4 capsules per day in divided doses or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, egg, dairy, peanuts, soy, 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® is a registered trademark of Albion, Inc. Activin® is a registered trademark of Dry Creek Nutrition, Inc. This product was sealed for your protection. Do not use if outer logopedic neck seal or printed inner-seal are missing or damaged. † 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.

Label ID L-OMP100-534060-C

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Dietary Supplement Product #534S

60 Capsules

Because Efficacy Matters™

Prolo Max

Supplement Facts	Amount Per Serving	% Daily Value
Serving Size 4 Capsules Amount Per Container: 15		
4 capsules contain		
Vitamin C (as Ascorbate)	160 mg	267%
Magnesium (as Ascorbate)	40 mg	10%
Manganese (as Chelazome)†	2 mg	100%
Potassium (as Ascorbate)	20 mg	<1%
Methylsulfonylmethane	1000 mg	
L-Arginine USP	600 mg	
L-Proline USP	500 mg	
L-Cysteine HCl Monohydrate USP	250 mg	
Gotu Kola (Aerial Portion) Extract 4:1	250 mg	
Horsetail Grass (Aerial Portion)	250 mg	
Activin (Grape Seed Extract)	50 mg	
Natural Vegetable Capsules	30 mg	
Purified Triterpenes		
*% 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.

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