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May 17, 2005

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

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, Women's Health

**Dietary Ingredients:** Vitamin B6 (as Pyridoxine HCl USP), Magnesium (as Ascorbate), GABA, Glycine USP, Cramp Bark, Dong Quai Root Extract (Standardized to contain 1% Ligustilides), Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

**Dietary Supplement Name:** GABAnol

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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Ortho Molecular Products GABAnol  
5/17/2005  
Page 1 of 2



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**Attachment of GABAnol Labels**

Suggested Use. As a dietary supplement, Acute: 2 capsules three times per day. Chronic: 1 capsule three times 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. Do not consume this product if you are pregnant or nursing. Consult your physician for further information. 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.

Because Efficacy Matters™

# GABAnol

**Supplement Facts**

Serving Size 2 Capsules  
 Servings Per Container: 30

2 capsules contain	Amount Per Serving	% Daily Value
Vitamin B6	50 mg	2500%
(as Pyridoxine HCl USP <sup>™</sup> )		
Magnesium (as Ascorbate)	15 mg	4%
GABA	250 mg	*
Glycine USP <sup>™</sup>	225 mg	*
Cramp Bark	200 mg	*
Dong Quai Root Extract	150 mg	*
(Standardized to contain 1% Ligustilides)		
* % Daily Value not established		

Other ingredients: Water, vegetable capsule. The product may contain trace amounts of the following: Alcohol, Peanut, Soybean, Sesame, Methylcellulose, Cellulose and Silicon Dioxide. The product was sealed in your presence. Do not use if outer top layer break seal or inner seal is missing or damaged.

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Label ID L-QM100-555060-0  
 Also Excellent for

60 Capsules

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