



May 18, 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 2004

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:** Gastrointestinal Support

**Dietary Ingredients:** Betaine HCl USP, Pepsin 1:3,000, Natural gelatin capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

**Dietary Supplement Name:** Betaine & Pepsin

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 Betaine & Pepsin  
5/18/2005  
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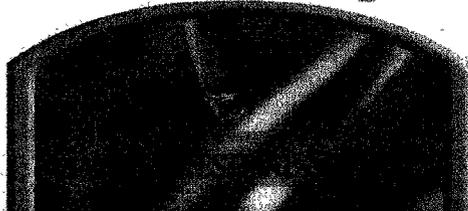


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Attachment of Betaine & Pepsin Labels



# Betaine & Pepsin



| Supplement Facts            |                    |               |
|-----------------------------|--------------------|---------------|
| Serving Size 2 Capsules     |                    |               |
| Servings Per Container: 112 |                    |               |
| 2 capsules contain          | Amount Per Serving | % Daily Value |
| Betaine HCl USP             | 1,040 mg           | *             |
| Pepsin 1:3,000              | 208 mg             | *             |

\* % Daily Value not established

Other Ingredients: Natural gelatin capsules. This product may contain one or more of the following: Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose and Silicon Dioxide. This product was sealed for your protection. Do not use if outer logoed neck seal or 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.

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

**Suggested Use:** As a dietary supplement, 1 capsule before each meal 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.  
 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.  
**Caution:** This product contains a desiccant. For best results, keep the desiccant in the bottle until all contents are consumed. Do NOT EAT DESICCANT.  
 KEEP CONTAINER TIGHTLY CLOSED. STORE AT ROOM TEMPERATURE.  
 KEEP OUT OF REACH OF CHILDREN  
 Label ID L-GMP100-543225-B



Dietary Supplement Product #543

225 Capsules

OrthoMolecularProducts.com