



August 3, 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

0123 5 SEP 22 P2:19

AUG - 9 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: Gastrointestinal Support, Immune Health

Dietary Ingredients: Lactobacillus acidophilus, Lactobacillus paracasei, Bifidobacterium bifidum, Bifidobacterium lactis, Lactobacillus plantarum, Lactobacillus rhamnosus, Saccharomyces boulardii, Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicic Dioxide.

Dietary Supplement Name: Ortho Biotic

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 Ortho Biotic
8/3/2005
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Attachment of Ortho Biotic Labels

Suggested Use: As a dietary supplement, 1 capsule per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg, peanuts, 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. This product was sealed for your protection. Do not use if outer logoed neck seal or inner seal are missing or damaged.

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Label ID L-OMP100-527030 A

Also Excellent for:

Ortho Biotic

Because Efficacy Matters™

Supplement Facts
 Serving Size 1 Capsule
 Servings Per Container: 30

	Amount Per Serving	% Daily Value
1 capsule contains:		
Proprietary Blend	20 billion CFU**	
Lactobacillus acidophilus		
Lactobacillus paracasei		
Bifidobacterium bifidum		
Bifidobacterium lactis		
Lactobacillus plantarum		
Lactobacillus rhamnosus		
Saccharomyces boulardii	2 billion CFU**	

** % Daily Value not established

Other ingredients: Natural vegetable capsules. This product may contain one or more of the following: Acetyl L-Carnitine, Magnesium Stearate, Microcrystalline Cellulose and Silicon Dioxide. † 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. †† Only when used.

Dietary Supplement, Product #527 30 Capsules

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