



August 3, 2005

Ortho Molecular Products Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481
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800.332.2351
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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

0124 5 SEP 22 P2:19

RECEIVED
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, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Ortho Biotic Powder – 51 grams

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 Ortho Biotic Powder – 51 grams Labels

Supplement Facts

Serving Size: 1.7 grams (Approx. 1 scoop)
 Servings Per Container: 30

Amount Per % Daily	Serving Value
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: This product may contain one or more of the following: Ascorbyl Palmitate, Magnesium Stearate, Microcystine Colloidal, 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. ++ Colony forming Units.

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

OrthoMolecularProducts.com



Ortho Biotic Powder

Suggested Use: As a dietary supplement, add one scoop of Ortho Biotic Powder (1.7 g) to a glass of water or the beverage of your choice, stir and drink, 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 topped neck seal or inner seal are missing or damaged.

Also Excellent for:

6 15033-00528 3

Label # - JMF 100-32061-A
 Dietary Supplement - Product #528