



May 17, 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 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: Mastic Gum Extract, Bismuth Citrate, Berberine Sulfate, Ginger Root Extract (Standardized to contain 5% Gingerols), Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Pyloricil

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 Pyloricil

5/17/2005

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Attachment of Pyloricil Labels

Suggested Use As a dietary supplement, 1 capsule three times per day 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. This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.



Label ID L-CMP100-847090-A

Dietary Supplement Product #847



Pyloricil



Also Excellent for:

Supplement Facts

Serving Size: 3 Capsules
 Servings Per Container: 30

3 capsules contain	Amount Per Serving	% Daily Value
Mastic Gum Extract	1000 mg	*
Bismuth Citrate	250 mg	*
Berberine Sulfate	100 mg	*
Ginger Root Extract (Standardized to contain 5% Gingerols)	100 mg	*

* % 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

*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

OrthoMolecularProducts.com