



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

Dietary Ingredients: Glutamic Acid, Betaine HCl, Pancreatin 6X, Pepsin, Ox Bile Extract, Pancrelipase, Papain, Bromelain, Amylase, Dicalcium Phosphate, Magnesium Stearate, Sorbitol, Pharmaceutical lac glaze.

Dietary Supplement Name: Ortho Digestzyme

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 Digestzyme Labels

Suggested Use: As a dietary supplement, 1-2 tablets 15 minutes before meals 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. This product contains the following potential allergens: Pineapple/ Bromelain and Plant and Animal Enzymes. 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. Label ID L-OMP100-532090-B

Because Efficacy Matters[®]

Ortho Digestzyme

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

Supplement Facts	
Serving Size 1 Tablet	
Servings Per Container: 90	
	Amount Per % Daily
1 tablet contains:	Serving Value
Glutamic Acid	110 mg *
Betaine HCl	100 mg *
Pancreatin 6X	100 mg *
Pepsin	100 mg *
Ox Bile Extract	60 mg *
Pancrelipase	50 mg *
Papain	50 mg *
Bromelain	40 mg *
Amylase	30 mg *
* % Daily Value not established	

Other ingredients: Dicalcium Phosphate, Magnesium Stearate, Sorbitol and Pharmaceutical Icc glaze. 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.

Suggested Use: As a dietary supplement, 1-2 tablets 15 minutes before meals 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. This product contains the following potential allergens: Pineapple/Bromelain and Plant and Animal Enzymes. 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. Label ID L-OMP100-532180-B

Because Efficacy Matters[®]

Ortho Digestzyme

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

Supplement Facts		
Serving Size 1 Tablet		
Servings Per Container: 180		
	Amount Per	% Daily
1 tablet contains:	Serving	Value
Glutamic Acid	110 mg *	*
Betaine HCl	100 mg *	*
Pancreatin 6X	100 mg *	*
Pepsin	100 mg *	*
Ox Bile Extract	60 mg *	*
Pancrelipase	50 mg *	*
Papain	50 mg *	*
Bromelain	40 mg *	*
Amylase	30 mg *	*
* % Daily Value not established		

Other ingredients: Dicalcium Phosphate, Magnesium Stearate, Sorbitol and Pharmaceutical Icc glaze.
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