



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: Cardiovascular Support, Muscular / Skeletal Support, Immune System

Dietary Ingredients: Pancreatin 6X, Papain, Bromelain, Rutin, Thymus, Trypsin, Amylase, Lipase, Lysozyme, Cellulase, Alpha Chymotrypsin, Dicalcium Phosphate, Magnesium Stearate, Sorbitol, Pharmaceutical lac glaze.

Dietary Supplement Name: Vasuczyme

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 Vasuczyme
5/17/2005
Page 1 of 2



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Attachment of Vascuzyme Labels

SUGGESTED USE: As a dietary supplement, 2-4 tablets three times per day on an empty stomach 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 & 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. **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.

† 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.
 Label ID L-OMP100-533180-B

Also Excellent for:



Dietary Supplement Product #5331



Vascuzyme

BECAUSE EFFICACY MATTERS

180 Tablets

Supplement Facts

Serving Size 1 Tablet
 Servings Per Container: 180

1 Tablet contains:	Amount Per Serving	% Daily Value
Pancreatin 6X	200 mg	*
Papain	100 mg	*
Bromelain	75 mg	*
Rutin	60 mg	*
Thymus	35 mg	*
Trypsin	35 mg	*
Amylase	15 mg	*
Lipase	15 mg	*
Lysozyme	10 mg	*
Cellulase	2 mg	*
Alpha Chymotrypsin	1 mg	*

* % Daily Value not established

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

Other ingredients: Dicalcium phosphate, magnesium stearate, sorbitol and pharmaceutical grade.
 This product was sealed for your protection. Do not use if outer top/bottom seal or inner seal are missing or damaged.

SUGGESTED USE: As a dietary supplement, 2-4 tablets three times per day on an empty stomach 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 & 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. **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.

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Label ID L-OMP100-533360-B



Dietary Supplement Product #5333A

Also Excellent for:



Vascuzyme

BECAUSE EFFICACY MATTERS

360 Tablets

Supplement Facts

Serving Size 1 Tablet
Servings Per Container: 360

	Amount Per Serving	% Daily Value
1 Tablet contains:		
Pancreatin 6X	200 mg	*
Papain	100 mg	*
Bromelain	75 mg	*
Rutin	60 mg	*
Thymus	35 mg	*
Trypsin	35 mg	*
Amylase	15 mg	*
Lipase	15 mg	*
Lysozyme	10 mg	*
Cellulase	2 mg	*
Alpha Chymotrypsin	1 mg	*

* % Daily Value not established

Other Ingredients: Dicalcium phosphate, magnesium stearate, sorbitol and pharmaceutical lac glaze.

This product was sealed for your protection. Do not use if outer logoad neck seal or inner-seal are missing or damaged.