



February 18, 2005

Ortho Molecular Products Inc  
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Stevens Point, WI 54481  
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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

1137 E  
FEB 23 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.

**Name of Manufacturer:** Ortho Molecular Products, Inc.  
3017 Business Park Drive  
P.O. Box 1060  
Stevens Point, WI 54481

**Statement Text:** Cardiovascular Health

**Dietary Ingredients:** Vitamin E, Nattokinase, Rice Bran Oil, Gelatin, Purified Water, Lecithin, Yellow Beeswax, Turmeric Powder, & Titanium Dioxide.

**Dietary Supplement Name:** Nattokinase

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,

Deborah Zurawski  
Quality Assurance Manager  
Ortho Molecular Products

975 0162 LET 1569

Suggested Use: As a dietary supplement, 1-2 soft gel capsules 2 times per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, 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. WARNING: Patients using Warfarin (Coumadin) should contact their health care professional before using this product. 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.



**Nattokinase**

**Supplement Facts**

Serving Size 1 Soft Gel  
Servings Per Container: 90

1 soft gel contains	Amount Per Serving	% Daily Value
Vitamin E	10 IU	33%
Nattokinase**	50 mg	*

\* % Daily Value not established  
\*\* 20,000 Fibrinolytic Units per gram at time of manufacture.

Other Ingredients: Rice Bran Oil, Gelatin, Glycerin, Purified Water, Lecithin, Yellow Beeswax, Turmeric Powder and Titanium Dioxide.

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

This product was sealed for your protection. Do not use if outer top/bottom seal or inner seal are missing or damaged.



Label ID L-GMP100-840090-B

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Dietary Supplement Product #840

90 Soft Gel Capsules