



May 18, 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 Health, Daily Essentials

**Dietary Ingredients:** Inositol Hexaniacinate, Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

**Dietary Supplement Name:** Inositol Hexaniacinate

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 Inositol Hexaniacinate 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, 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. 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.



**Inositol Hexaniacinate**

**Supplement Facts**

Serving Size 1 Capsule  
 Servings Per Container: 60

1 capsule contains	Amount Per Serving	% Daily Value
Inositol Hexaniacinate	650 mg	*

\* % Daily Value not established

Other Ingredients: Natural vegetable capsules. This product may contain one or more of the following: Ascoroyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose and Silicon Dioxide. This product was sealed for your protection. Do not use if outer logoped neck seal or inner-seal are missing or damaged.



Label ID L-OMP100-115060-C

Also Excellent for:



Dietary Supplement Product #115

60 Capsules

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

OrthoMolecularProducts.com

Because Efficacy Matters™ Because Efficacy Matters™

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, 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.

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-OMP100-116180-C



**Inositol Hexaniacinate**



Also Excellent for:



Dietary Supplement Product #115A

180 Capsules

Ortho Molecular Products Inositol Hexaniacinate

5/18/2005

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Efficient Matters. Because Efficient Matters. Because Efficient Matters.

### Supplement Facts

Serving Size 1 Capsule  
Servings Per Container: 180

1 capsule contains	Amount Per Serving	% Daily Value
Inositol Hexaniacinate	650 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. This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.

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

OrthoMolecularProducts.com