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June 29, 20

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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

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: Time Release Niacin (Niamax), Vegetable Stearine, Carnauba Wax, Magnesium Stearate (Veg), Silica.

Dietary Supplement Name: Time Release Niacin

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 Time Release Niacin
6/29/20



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Attachment of Time Release Niacin Labels

Suggested Use: As a dietary supplement, 3 tablets per day in divided doses with a meal 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. Do not consume this product if you are pregnant or nursing. Consult your physician for further information. 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. This product is designed to release Niacin over a 6-8 hour period to minimize the amount of flushing. A small percentage of people may still experience harmless flushing while taking this product. † 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.



ORTHOMOLECULAR PRODUCTS
 Because Efficacy Matters™

Time Release Niacin

Supplement Facts
 Serving Size: 1 Tablet
 Servings Per Container: 90

1 tablet contains	Amount Per Serving	% Daily Value
Time Release Niacin (Nimax™)	500 mg	2500%

* % Daily Value not established

Other Ingredients: Vegetable Stearines, Carnauba Wax, Magnesium Stearate (Veg) and Silica. This product was sealed for your protection. Do not use if outer toped neck seal or inner seal are missing or damaged. Nimax is a trademark of Lonza, Inc. KEEP CONTAINER TIGHTLY CLOSED. STORE AT ROOM TEMPERATURE. KEEP OUT OF REACH OF CHILDREN. Label ID L-OMP100-146080-B
 Mfg. by: Ortho Molecular Products, Inc. 3017 Business Park Drive Stevens Point, WI 54481
 OrthoMolecularProducts.com

Also Excellent for: Daily Estrogens

6 15033 00146 9
 Dietary Supplement Product #746 90 Tablets