



May 18, 2005

1 4 4 1 5 JUN -3 P 2 :11

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 2004

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: Premium Vascular Health, Cardiovascular Health

Dietary Ingredients: Time Release Niacin (Niamax), Plant Sterol Esters, Pantethine, EPA, DHA, Gelatin, Natural Mixed Tocopherols 90%, Vegetable Stearine, Carnauba Wax, Magnesium Stearate (Veg), Silica, Natural vegetable capsules, Glycerin, Purified Marine Triglyceride Concentrate, Purified Water.

Dietary Supplement Name: Triplichol with 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

975 0162

LET

16 249

Ortho Molecular Products Triplichol with Niacin

5/18/2005

Page 1 of 2



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

Attachment of Triplichol with Niacin Labels



Suggested Use: As a dietary supplement, 2 packets per day 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. This product contains the following potential allergen: Fish. Do not consume if you are pregnant or nursing. Consult your physician for further information. 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.

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.

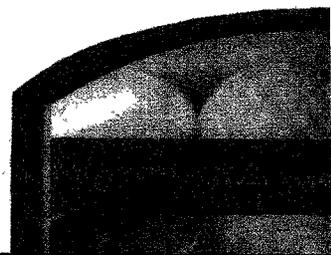
KEEP CONTAINER TIGHTLY CLOSED. STORE AT ROOM TEMPERATURE. KEEP OUT OF REACH OF CHILDREN.

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

Label ID L-OMP100-353060-B



Tripl
Premium Vascul



Dietary Supplement Product #353

60 Pa

TO
ECULAR
DUCTS
y Matters®

cholTM
with Niacin
or Health[†] Pack



“Products containing at least 0.65 g per serving of plant sterol esters, taken twice daily with meals for a daily total intake of at least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease.”

“Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of Triplichol provides 1.44 grams of EPA and DHA omega-3 fatty acids.”

Supplement Facts		
Serving Size 2 Packets		
Servings Per Container: 30		
	Amount Per Serving	% Daily Value
2 packets contain		
Total Calories	13.14	
Calories from Fat	13.14	
Total Fat	1.46 g	2.24%*
Time Release Niacin (Niamax TM)	1 g	5000%
Plant Sterol Esters	1.3 g	**
Pantethine	900 mg	**
EPA	840 mg	**
DHA	600 mg	**

* % Daily Values are based on 2,000 calorie diet.
** % Daily Value not established

Other Ingredients: Gelatin, Natural Mixed Tocopherols 90%, Vegetable Stearine, Carnauba Wax, Magnesium Stearate (Veg), Silica, Natural Vegetable Capsules, Glycerin, Purified Marine Triglyceride Concentrate and Purified Water. NiamaxTM is a registered trademark of Lonza, Inc. †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.

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