

May 18, 2005

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).

JUN -3 P2:11

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

1442

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Dietary Ingredients: Plant Sterol Esters, Pantethine, EPA, DHA, Gelatin, Natural Mixed Tocopherols 90%, Natural vegetable capsules, Vegetable Glycerin, Purified Marine Triglyceride Concentrate, Purified Water.

Dietary Supplement Name: Triplichol

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,

Musca Stager

Melissa Slager Document Control / Training Manager Ortho Molecular Products

LET 16250 975 0162

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Attachment of Triplichol Labels

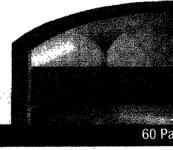
Suggested Use: As a dietary supplement, 2 packets per day with a meal or as recommended by your health care professional.

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.

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



Tripl Premium Vascu



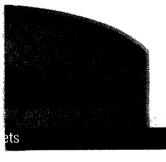
Label ID L-OMP100-354060-B



Dietary Supplement Product #354

Ortho Molecular Products Triplichol 5/18/2005 Page 2 of 2 iO CULAR)UCTS ' Matters"

chol[™] ir 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

Obivinger er opnitarier	. 00	
	Amount Per	% Daily
2 packets contain	Serving	Value
Total Calories	13.14	
Calories from Fat	13.14	
Total Fat	1.46 g	2.24%*
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 Values are based on 2,000 calone diet. ** % Daily Value not established

Other Ingredients: Gelatin, Natural Mixed Tocopherols 90%, Natural Vegetable Capsules, Vegetable Glycerin, Purified Marine Triglyceride Concentrate and Purified Water.

†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