



June 1, 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

1757 5 JUN 22 P2:20
JUN 8 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

Dietary Ingredients: Sterol Esters, Gelatin, Natural Mixed Tocopherols 90%.

Dietary Supplement Name: Plant Sterols

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

07S 0162 LET 16293



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 Plant Sterols Labels

Suggested Use. As a dietary supplement, 1-2 soft gel capsules per day 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. 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.



Plant Sterols



Nutrition Facts

Serving Size 1 Soft Gel
 Servings Per Container: 60

1 Soft Gel contains	Amount Per Serving	% Daily Value
Total Calories	6.57	0%
Calories from Fat	6.57	0%
Total Fat	0.73 g	1%*
Sterol Esters	650 mg	**

*% Daily Values are based on a 2000 calorie diet.
 ** Daily Value not established

Other Ingredients: Gelatin, Natural Mixed Tocopherols 90%
 This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.



6 15033 00429 3

Label ID L-OMP100-429060-B

Dietary Supplement Product #429

60 Soft Gel Capsules

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

OrthoMolecularProducts.com