



May 17, 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

Dietary Ingredients: Chromium (as ChromeMate), Inositol Hexaniacinate, Gugul Resin (Standardized to contain 2.5% Gugulsterones), Guar Gum, Artichoke Leaf Extract (Standardized to contain 5% Cynarin), Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Lipitrol

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

97S 0162 LET 16237



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Attachment of Lipitrol Labels

Suggested Use: As a dietary supplement, 1 capsule three times per day on an empty stomach or as recommended by your health care professional. For best results, consult your health care professional about using Fiber Plus with Lipitrol. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, yeast, artificial colors and flavors. This product contains the following allergens: Asteracea. 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 was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.

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.



Lipitrol

Supplement Facts

Serving Size 3 Capsules
 Servings Per Container: 30

3 capsules contain	Amount Per Serving	% Daily Value
Chromium (as Chromelate®)	200 mcg	167%
Inositol Hexaniacinate	1350 mg	*
Gugul Resin (Standardized to contain 2.5% Gugulsterones)	500 mg	*
Guar Gum	225 mg	*
Artichoke Leaf Extract (Standardized to contain 5% Cynarin)	150 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.

Chromelate® is a registered trademark of Health Nutraceuticals, Inc.



6 15033 00530 6 Label ID L-DMP100-530090-C

Dietary Supplement Product #530

90 Capsules

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