

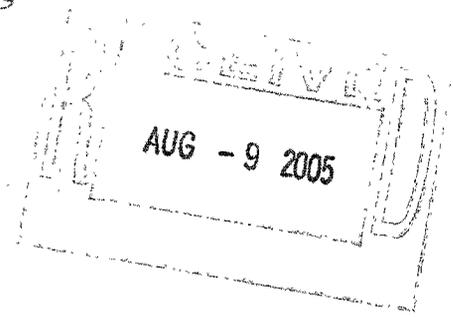


August 3, 2005

0126 5 SEP 22 P2:19

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: Immune Health

Dietary Ingredients: N-Acetyl-L-Cysteine USP, Andrographis Paniculata Leaf & Stem Extract (Standardized to contain 20% Andrographilides), Thyme (Aerial Portion) Extract 5:1, Tumeric Root Extract (Standardized to contain 95% Curcumin), Eleuthero (Siberian Ginseng) Root Extract (Standardized to contain 0.8% Eleutherside), Bromelain (2,400 GDU/g), Berberine Sulfate, Licorice Root Extract (Standardized to contain 12% Glycyrrhizin), Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Sinatrol

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 Sinatrol
8/3/2005
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Attachment of Sinatrol Labels

Suggested Use: As a dietary supplement, 3 capsules per day or as recommended by your health care professional. Formulated to be free of allergens derived from: *Gluten, egg, dairy, peanuts, soy, yeast, artificial colors and flavors.* This product contains the following potential allergens: *Pineapple/Bromelain.* 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. 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. This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.
 Label ID: L-OMP100-516060-B



Dietary Supplement Product #516



Sinatrol

60 Capsules

Supplement Facts

| Serving Size: 3 Capsules | | Amount Per % Daily | |
|--|--------|---------------------------------|-------|
| Servings Per Container: 20 | | Serving | Value |
| 3 Capsules contain: | | | |
| N-Acetyl-L-Cysteine USP | 750 mg | | * |
| Andrographis Paniculata Leaf & Stem Extract (Standardized to contain 20% Andrographolides) | 300 mg | | * |
| Thyme (Aerial Portion) Extract 5:1 | 300 mg | | * |
| Turmeric Root Extract | 300 mg | | * |
| (Standardized to contain 95% Curcumin) | | | |
| Eleuthero (Siberian Ginseng) Root Extract (Standardized to contain 0.8% Eleutheroside) | 250 mg | | * |
| Bromelain (2,400 GDU/g) | 200 mg | | * |
| Berberine Sulfate | 100 mg | | * |
| Licorice Root Extract (Standardized to contain 12% Glycyrrhizin) | 100 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.

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