



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: Gastrointestinal Health

Dietary Ingredients: Milk Thistle Seed Extract (Standardized to contain 80% Silymarin), Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Silymarin Forte

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 Silymarin Forte
5/17/2005
Page 1 of 2



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Attachment of Silymarin Forte Labels

Suggested Use: As a dietary supplement, 1 capsule three times 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.

Label ID L-OMP100-906000-B

6 15033 00806 2

Also Excellent for:

ORTHOMOLECULAR PRODUCTS
Because Efficacy Matters™

Silymarin Forte

BECAUSE EFFICACY MATTERS

60 Capsules

Supplement Facts
Serving Size: 1 Capsule
Servings Per Container: 60

1 capsule contains	Amount Per Serving	% Daily Value
Milk Thistle Seed Extract (Standardized to contain 80% Silymarin)	200 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. This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.

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

†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.

Suggested Use: As a dietary supplement, 1 capsule three times 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.

Label ID L-OMP100-806030-B

6 15033 01806 1

Also Excellent for:

ORTHOMOLECULAR PRODUCTS
Because Efficacy Matters™

Silymarin Forte

BECAUSE EFFICACY MATTERS

90 Capsules

Supplement Facts
Serving Size: 1 Capsule
Servings Per Container: 90

1 capsule contains	Amount Per Serving	% Daily Value
Milk Thistle Seed Extract (Standardized to contain 80% Silymarin)	200 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.

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Suggested Use: As a dietary supplement, 1 capsule three times 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.

Label ID L-OMP100-806120-B

6 15033 02806 0

Also Excellent for:

ORTHOMOLECULAR PRODUCTS
Because Efficacy Matters™

Silymarin Forte

BECAUSE EFFICACY MATTERS

120 Capsules

Supplement Facts
Serving Size: 1 Capsule
Servings Per Container: 120

1 capsule contains	Amount Per Serving	% Daily Value
Milk Thistle Seed Extract (Standardized to contain 80% Silymarin)	200 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.

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

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