

Monday, August 23, 2004

Ortho Molecular Products Inc
3017 Business Park Drive
PO 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

9/27/04

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: Inflamm-a-BLOX

Dietary Ingredients: Skullcap Root Extract (Standardized to contain 30% flavones, *S. baicalensis*), Bee Propolis Extract 2X, Turmeric Root Extract (Standardized to contain 95% Curcumin), Graminex G60 (Pollen Extract), Ascorbyl Palmitate, Microcrystalline Cellulose, and Silicon Dioxide.

Dietary Supplement Name: Inflamm-a-BLOX

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,

Deborah Zurawski 8-23-04

Deborah Zurawski
Quality Assurance Manager
Ortho Molecular Products

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Ortho Molecular Products Inflamm-a-BLOX

8/23/2004

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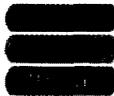
Attachement of Inflamm-a-bLOX Labels

Suggested Use As a dietary supplement, 3 capsules 2 times per day or as recommended by your health care professional
Formulated to be free of the following Gluten, egg, dairy, peanuts, soy, yeast, artificial colors and flavors
 This product contains the following potential allergens: Pollen
 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 inner-seal is missing or damaged.
 Label ID L-CMP100-607090-A



Dietary Supplement Product #607

Also Excellent for:



Inflamm-a-bLOX[†]



90 Capsules

Supplement Facts

Serving Size 6 Capsules
 Servings Per Container 15

6 capsules contain	Amount Per Serving	% Daily Value
Skullcap Root Extract (Standardized to contain 30% flavones, <i>S. baicalensis</i>)	1400 mg	*
Bee Propolis Extract 2X	950 mg	*
Turmeric Root Extract (Standardized to contain 95% Curcumin)	850 mg	*
Graminex G60 (Pollen Extract)	700 mg	*

* % Daily Value not established

Other Ingredients: Natural vegetable capsules. This product may contain one or more of the following: Ascorbyl Palmitate, Microcrystalline Cellulose and Silicon Dioxide.

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

†This statement has 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, 3 capsules 2 times per day or as recommended by your health care professional
Formulated to be free of the following Gluten, egg, dairy, peanuts, soy, yeast, artificial colors and flavors
 This product contains the following potential allergens: Pollen
 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 inner-seal is missing or damaged.

Label ID L-CMP100-607180-A

Also Excellent for:



Muscle Health



Dietary Supplement Product #607A



Inflamm-a-bLOX[†]



180 Capsules

Supplement Facts

Serving Size 6 Capsules
 Servings Per Container 30

6 capsules contain	Amount Per Serving	% Daily Value
Skullcap Root Extract (Standardized to contain 30% flavones, <i>S. baicalensis</i>)	1400 mg	*
Bee Propolis Extract 2X	950 mg	*
Turmeric Root Extract (Standardized to contain 95% Curcumin)	850 mg	*
Graminex G60 (Pollen Extract)	700 mg	*

* % Daily Value not established

Other Ingredients: Natural vegetable capsules. This product may contain one or more of the following: Ascorbyl Palmitate, Microcrystalline Cellulose and Silicon Dioxide.

†This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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