



Tuesday, August 19, 2003

Ortho Molecular Products Inc
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481
715.342.9881 Phone
800.332.2351
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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

DEC - 1 2003

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 label).

Name of Manufacturer: Ortho Molecular Products, Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481

Statement Text: For occasional sleeplessness...Natural ZZZs. Good Night

Dietary Ingredients: Valerian Root Extract, Jujube Seed Extract, Passion Flower (aerial portion) Extract, L-Theanine, Microcrystalline Cellulose, Magnesium Stearate

Dietary Supplement Name: Natural ZZZs

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,

Dean W. Kramer
Director of Quality
Ortho Molecular Products

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Suggested Use: As a dietary supplement, take 2 capsules 1 hour before sleep 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.

As with all dietary supplements, some individuals may not tolerate or be allergic to the ingredients used. Please read the ingredients panel carefully prior to ingestion.

Cease taking this product and consult your physician if you have negative reactions upon ingestion. Do not consume this product if you are pregnant or nursing. Consult your physician for further information.

Keep container tightly closed. Store at room temperature. Keep out of reach of children.



For occasional sleeplessness...

NATURAL

Good Night.

Supplement Facts	
Serving Size: 2 Capsules	% Daily Value
Servings Per Container: 15	
2 Capsules Contain	
Valerian Root Extract	450 mg *
Standardized to contain 0.8% Valerianic Acids	
Jujube Seed Extract	300 mg *
Standardized to contain 2% Irogonic Saponins	
Passionflower (aerial portion) Extract	200 mg *
Standardized to contain 3.5% Flavonoids	
L-Theanine	100 mg *
*Daily Value not established.	

See product label for full details. Ortho Molecular Products, Inc. is not responsible for any adverse effects or allergic reactions to this product. Do not use if outer seal is broken, inner seal is missing or damaged. 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.