



August 3, 2005

0128-5 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

RECEIVED
AUG - 9 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, Immune Health

Dietary Ingredients: Olive Leaf Extract (Standardized to contain 20% Oleuropein), Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Olive Leaf Extract

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 Olive Leaf Extract
8/3/2005
Page 1 of 2