



June 29, 2005

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

JUL 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: Muscular / Skeletal Health, Gastrointestinal Health

Dietary Ingredients: Bromelain (2,400 GDU/g), Papain, Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Bromelain 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,

A handwritten signature in cursive script that reads 'Melissa Slager'.

Melissa Slager
Document Control / Training Manager
Ortho Molecular Products

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LET 16496

Ortho Molecular Products Bromelain Forte
6/29/2005
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Attachment of Bromelain Forte Labels

Suggested Use. As a dietary supplement, 1-2 capsules three times per day or as recommended by your health care professional. More as needed for excessive physical strain. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. This product contains the following potential allergens: Pineapple/Bromelain. 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 are missing or damaged. Label ID L-QMP100-545090-B



Bromelain Forte



Supplement Facts

Serving Size 1 Capsule
 Servings Per Container: 90

	Amount Per Serving	% Daily Value
1 capsule contains		
Bromelain (2,400 GDU/g)	500 mg	*
Papain	30 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

†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.



Also Excellent for:



Dietary Supplement Product #545

90 Capsules

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