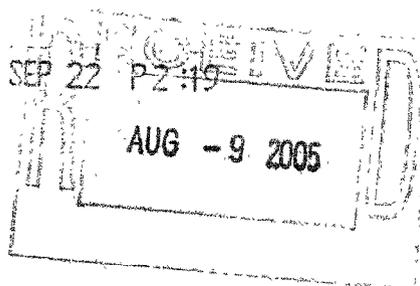




August 3, 2005

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

0125 5 SEP 22 PZ:19  
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



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:** Immune Health, Women's Health

**Dietary Ingredients:** Uva Ursi Leaf Extract (Standardized to contain 20% Arbutin), Berberine Sulfate, Bromelain (2,400 GDU/g), Marshmallow Root, Buchu Leaf Extract 4:1, Bladderwrack Leaf, Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

**Dietary Supplement Name:** Cystistatin

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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LET

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Ortho Molecular Products Cystistatin  
8/3/2005  
Page 1 of 2



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Attachment of Cystistatin Labels

**Suggested Use:** As a dietary supplement, 1-2 capsules three times per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. This product contains the following potential allergens: Pineapple/Bromelain. Do not consume this product if you are pregnant or nursing. Consult your physician for further information. 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 topged neck seal or inner seal are 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. Label ID L-OMP100-561030-B

Because Efficacy Matters™

# Cystistatin

6 15033 00561 0

Also Excellent for:

Dietary Supplement Product #561

30 Capsules

**Supplement Facts**

Serving Size 1 Capsule  
Servings Per Container: 30

1 capsule contains	Amount Per Serving	% Daily Value
Uva Ursi Leaf Extract	325 mg	*
(Standardized to contain 20% Arbutin)		
Berberine Sulfate	100 mg	*
Bromelain (2,400 GDU/g)	50 mg	*
Marshmallow Root	50 mg	*
Buchu Leaf Extract 4:1	40 mg	*
Bladderwrack Leaf	40 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.  
 Mfg. by Ortho Molecular Products, Inc. 3017 Business Park Drive Stevens Point, WI 54481  
 OrthoMolecularProducts.com

**Suggested Use:** As a dietary supplement, 1-2 capsules three times per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. This product contains the following potential allergens: Pineapple/Bromelain. Do not consume this product if you are pregnant or nursing. Consult your physician for further information. 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 topged neck seal or inner seal are 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. Label ID L-OMP100-561060-B

Because Efficacy Matters™

# Cystistatin

6 15033 01561 9

Also Excellent for:

Dietary Supplement Product #561A

60 Capsules

**Supplement Facts**

Serving Size 1 Capsule  
Servings Per Container: 60

1 capsule contains	Amount Per Serving	% Daily Value
Uva Ursi Leaf Extract	325 mg	*
(Standardized to contain 20% Arbutin)		
Berberine Sulfate	100 mg	*
Bromelain (2,400 GDU/g)	50 mg	*
Marshmallow Root	50 mg	*
Buchu Leaf Extract 4:1	40 mg	*
Bladderwrack Leaf	40 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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 OrthoMolecularProducts.com