



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

Office of Special Nutritional (HFS-450) 0122 5 SEP 22 P2:18  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

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:** Immune Health

**Dietary Ingredients:** Vitamin A (as Palmitate, Betene, Natural Mixed Carotenoids), Vitamin C (as Ascorbic Acid USP, Acerola Fruit Extract), Vitamin B12 (as Methylcobalamin), Pantothenic Acid (as d-Calcium Pantothenate), Zinc (as Chelazome Amino Acid Chelate), L-Lysine USP, Echinacea Purpurea (Aerial Portion) Extract 16:1, Pau D'Arco Inner Bark Extract 5:1, Acerola Fruit Extract (Standardized to contain 17% Vitamin C), Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

**Dietary Supplement Name:** Viracid

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 Viracid  
8/3/2005  
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Attachment of Viracid Labels

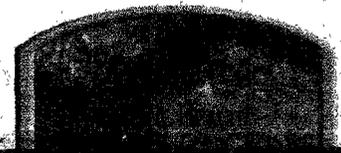
**Suggested Use:** As a dietary supplement, 1-2 capsules as needed or as recommended by your health care professional. Not to exceed 2 capsules every hour. Formulated to be free of allergens derived from: Gluten, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. This product contains the following potential allergens: Asteraceae. 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 logeod 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-OMP100-525040-B



Supplement Facts		
Serving Size 1 Capsule	Amount Per Serving	% Daily Value
Servings Per Container: 40		
1 capsule contains		
Vitamin A (as Palmitate)	15,000 IU	300%
Betacarotene, Natural Mixed Carotenoids	300 mg	500%
Vitamin C (as Ascorbic Acid USP, Acerola Fruit Extract)	2.5 mg	42%
Vitamin B12 (as Methylcobalamin)	2.5 mcg	42%
Pantothenic Acid (as D-Calcium Panthothinate)	10 mg	100%
Zinc (as Chelazone® Amino Acid Chelate)	4 mg	27%
L-lysine USP	100 mg	*
Echinacea Purpurea (Merial Puron) Extract 1:1	100 mg	*
Pau D'Arco (Liriodendron Toxicaria) Bark Extract 5:1	50 mg	*
Acerola Fruit Extract (Standardized to contain 17% Vitamin C)	25 mg	*
* % Daily Value not established		

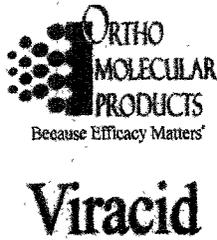


6 15033 00525 2  
 Dietary Supplement Product #525



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. 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 as needed or as recommended by your health care professional. Not to exceed 2 capsules every hour. 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: Asteraceae. 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 logeod neck seal or inner seal are missing or damaged.



Supplement Facts		
Serving Size 1 Capsule	Amount Per Serving	% Daily Value
Servings Per Container: 120		
1 capsule contains		
Vitamin A (as Palmitate)	15,000 IU	300%
Betacarotene, Natural Mixed Carotenoids	300 mg	500%
Vitamin C (as Ascorbic Acid USP, Acerola Fruit Extract)	2.5 mg	42%
Vitamin B12 (as Methylcobalamin)	2.5 mcg	42%
Pantothenic Acid (as D-Calcium Panthothinate)	10 mg	100%
Zinc (as Chelazone® Amino Acid Chelate)	4 mg	27%
L-lysine USP	100 mg	*
Echinacea Purpurea (Merial Puron) Extract 1:1	100 mg	*
Pau D'Arco (Liriodendron Toxicaria) Bark Extract 5:1	50 mg	*
Acerola Fruit Extract (Standardized to contain 17% Vitamin C)	25 mg	*
* % Daily Value not established		



6 15033 01525 1  
 Label ID L-OMP100-525120-C  
 Dietary Supplement Product #525A



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