



May 18, 2005

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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

MAY 25 2004

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: Cardiovascular Health, Daily Essentials

Dietary Ingredients: Vitamin E (as Mixed Tocopherols), Coenzyme Q10, Rice Bran Oil, Gelatin, Glycerin, Yellow Beeswax, Beta Carotene, Titanium, Oxide, Annato Extract, Water.

Dietary Supplement Name: CoQ-10

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

975 0162 LET 16 248



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Attachment of CoQ-10 Labels

Suggested Use: As a dietary supplement, 1 or more soft gel capsules per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. 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. † 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.



Supplement Facts		
Serving Size 1 Soft Gel		
Servings Per Container: 30		
1 soft gel contains	Amount Per Serving	% Daily Value
Vitamin E (as Mixed Tocopherols)	100 IU	333%
Coenzyme Q10	100 mg	*

Other Ingredients: Rice Bran Oil, Gelatin, Glycerin, Yellow Beeswax, Beta Carotene, Titanium Oxide, Annatto Extract and Water.

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



Label ID L-CMP100-120090-C
 Also Excellent for:
 Daily Essentials

Dietary Supplement Product #120

30 Soft Gel Capsules

Suggested Use: As a dietary supplement, 1 or more soft gel capsules per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. 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. † 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.



Supplement Facts		
Serving Size 1 Soft Gel		
Servings Per Container: 60		
1 soft gel contains	Amount Per Serving	% Daily Value
Vitamin E (as Mixed Tocopherols)	100 IU	333%
Coenzyme Q10	100 mg	*

Other Ingredients: Rice Bran Oil, Gelatin, Glycerin, Yellow Beeswax, Beta Carotene, Titanium Oxide, Annatto Extract and Water.

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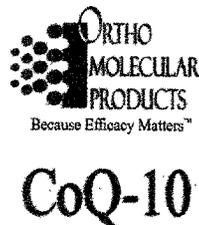


Label ID L-CMP100-120060-C
 Also Excellent for:
 Daily Essentials

Dietary Supplement Product #120A

60 Soft Gel Capsules

Suggested Use: As a dietary supplement, 1 or more soft gel capsules per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. 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. † 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.



Supplement Facts		
Serving Size 1 Soft Gel		
Servings Per Container: 120		
1 soft gel contains	Amount Per Serving	% Daily Value
Vitamin E (as Mixed Tocopherols)	100 IU	333%
Coenzyme Q10	100 mg	*

Other Ingredients: Rice Bran Oil, Gelatin, Glycerin, Yellow Beeswax, Beta Carotene, Titanium Oxide, Annatto Extract and Water. This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.

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



Label ID L-CMP100-120120-C
 Also Excellent for:
 Daily Essentials

Dietary Supplement Product #120C

120 Soft Gel Capsules