

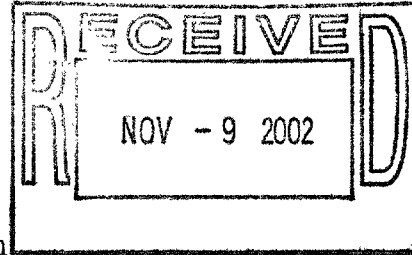


600 Boyce Road • Pittsburgh, PA 15205-9742 USA • (412) 494-0100 • FAX (412) 494-0155

Manufacturers and Distributors of Quality Nutritional Supplements for Over 40 Years.

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November 5, 2002



Office of Nutritional Product, Labeling and  
Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

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**RE: Section 403(r)(6) Notification**

Dear Sir or Madam:

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6), and implementing regulation 211 C.F.R. § 101.93, HVL Incorporated submits this notification that the following statements are included in labeling for the dietary supplement Qmelt™ Natural Coenzyme Q10:

Supports cardiovascular/circulatory health

Supports antioxidant defense

Supports energy production

CoQ10 is a nutrient vitally important for allowing cells to produce the energy needed for the body to function properly.

Sufficient amounts of CoQ10 are especially important to help maintain proper function of the heart, an organ that requires large amounts of energy.

CoQ10 also acts as a powerful antioxidant helping to fight free radicals in the body.

Lipid lowering drugs (statins) have been shown to deplete CoQ10 from the body. If you are currently taking a cholesterol lowering drug, you should consult with your health professional about the benefits of supplementing with CoQ10.

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Numerous clinical studies in hospitals and universities have documented its vital role in the production of energy in the body.

More specifically, CoQ10 is located in the body's mitochondria (the cell's powerhouse) where it participates in energy production.

The body's need for natural coenzyme Q10 as an essential nutrient is paramount in supporting all aspects of energy production and a healthy heart.

Numerous studies have shown that maintaining sufficient levels of natural coenzyme Q10 can positively support:

- Cardiovascular/circulatory health
- Immune system/antioxidant defenses
- Energy production

HVL Incorporated is the distributor for the dietary supplement. The address of HVL Incorporated is: 600 Boyce Road, Pittsburgh, PA 15205.

I certify that the information contained in this notification is complete and accurate and that HVL Incorporated has substantiation that the foregoing statements are truthful and not misleading.

Sincerely,



L. Douglas Lioon  
President and Chief Executive Officer

LDL/lrz

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