



September 10, 2004

SEP 21 2004

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

Re: SECTION 403(r)(6) NOTIFICATION

Dear Sir or Madam:

In accordance with the requirements of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Melaleuca, Inc., notifies FDA that it has begun using the following statements:

- Cellular protection with a healthy dose of broad-spectrum antioxidant.
- This broad spectrum antioxidant helps stabilize free radicals, preventing them from causing cellular damage. Made with a unique combination of mixed carotenoids and tocopherols derived from whole foods, CellWise provides free radical protection at the cellular level.
- Our broad-spectrum antioxidant includes the antioxidant power of mixed carotenoids derived from whole foods and mixed tocopherols to neutralize free radicals throughout your body. Plus, CellWise also includes a proprietary blend of alpha lipolic acid, L-glutamine, green tea, cocoa, and clove extracts—for even more free radical protection at the cellular level.
- Used by your body to manufacture vitamin A, carotenoids are essential for proper vision, they help protect the integrity of cells, and they assist white blood cell function.
- Tocopherols are vital for normal cell structure and red blood cell formation. They also boost immunity.
- Strengthens your cell membranes and helps form collagen—which is essential for healthy bones, ligaments, and blood vessels.
- Helps protect red blood cells and cell membranes.
- Helps promote message signals between your cells—as well as enhances bone health.
- Encourages normal cell division and normal functioning of the eyes, liver, kidneys, and reproductive organs.
- Nourishes your skin, bones, and cartilage—while enhancing the antioxidants’ effectiveness.
- CellWise’s proprietary antioxidant blend significantly boosts its antioxidant power.

These statements contain the statutory disclaimer. The name of the dietary supplement to which these statements apply is CellWise®, and the relevant dietary ingredients are vitamin C, calcium, zinc, selenium, copper, cocoa extract, green tea extract, L-glutamine, clove powder, alpha lipolic acid, blueberry powder, grape skin extract, rosemary powder, S-adenosyl-L-methionine, mixed carotenoids, mixed tocopherols,

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I certify that the foregoing is complete and accurate, and that Melaleuca, Inc., has substantiation that the statements are truthful and not misleading.

Very truly yours,

Melaleuca, Inc.



Jeff Wasden
V.P. Product Marketing