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Mr. Jeff Wasden  
V.P. of Product Marketing  
Melaleuca, Inc.  
3910 South Yellowstone Highway  
Idaho Falls, Idaho 83402-6003

Dear Mr. Wasden:

This is in response to your letter of April 26, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Melaleuca, Inc. is making the following claim, among others, for the products **Cell-Wise®** and **Cell-Wise Synthetic E™**:

“...stimulate white blood cell activity to protect the body from foreign invaders.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely diseases caused by pathogenic microorganisms. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10,7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

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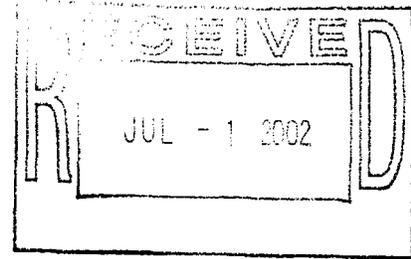
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Copies:

FDA, Center for **Drug** Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340



April 26, 2002

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S.W.  
Washington, DC 20204

**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:

- Help stop cell-damaging free radicals in their tracks. This broad-spectrum antioxidant works at the cellular level—targeting specific parts of your cells (as well as different types of cells) with powerful antioxidants like vitamins C and E, beta carotene, and the minerals zinc, selenium, and copper.
- Antioxidants are your cells' best friends. These specialized nutrients neutralize the damaging activity of free radicals by supplying the extra electrons they desperately seek.
- Nourishes respiratory tract; strengthens cell membranes; protects cells against toxins; helps promote message signals between cells; encourages normal cell division; protects cells **from** free radical damage; nourishes skin, bone, cartilage; enhances antioxidants' effectiveness; stimulates white blood cell activity to protect the body from foreign invaders.

These statements contain the statutory disclaimer. The names of the dietary supplements to which these statements apply are Cell-Wise@ and Cell-Wise@ Synthetic E, and the relevant dietary ingredients are the vitamins C, E, and beta carotene and the minerals zinc, selenium, copper, and manganese.

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. of Product Marketing

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