



MAR 17 1998

Rec'd 3/26/98 jib

Mr. Brett L. Merrell
V.P. Product Marketing
Melaleuca, Inc.
3910 South Yellowstone Highway
Idaho Falls, Idaho 83402-6003

Dear Mr. Merrell:

This is in response to your letter of December 23, 1997 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:

“...many people take increased levels of vitamin C for greater protection during the cold season.”

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 these products suggest that they are intended to prevent, treat or mitigate disease, namely the common cold. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

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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

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, KCarson)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:3/12/98

Init:GCF-1:LNickerson:3/12/98

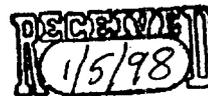
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Melaleuca, Inc.

3910 South Yellowstone Hwy
Idaho Falls, Idaho 83402-6003
208 522-0700

December 23, 1997



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:

Either Cell-Wise or Cell-Wise Synthetic E, when combined with a good diet and regular exercise, can help guard your health and reduce your risk for degenerative conditions.

The synergistic activity of this three-fold vitamin blend ensures broad cellular protection.

Your Serious Antioxidant Protection.

Vitamins C, E, and beta carotene--you'll find all three in Cell-Wise. Each is a proven antioxidant and is provided at the recommended dosage which research has shown will significantly protect the cells in your body.

With Cell-Wise, your cells have more protection on their side, allowing them to fight off possible health enemies much more effectively.

In addition to these three proven vitamins, Cell-Wise contains four powerful minerals: zinc, selenium, copper, and manganese. Together, these four minerals help to boost the body's own supply of protective nutrients, lowering the risk for degenerative conditions and raising the potential for overall good health.

Numerous scientific studies have proven that individuals who took more vitamin E, beta carotene, or vitamin C had lower risks for degenerative heart conditions or other similar unhealthy conditions, and had overall healthier hearts.

Vitamin C helps to form collagen, which is essential for healthy bones, gums, ligaments, and blood vessels. It also helps maintain an effective immune system. For example, many people take increased levels of vitamin C for greater protection during the cold season.

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Vitamin E is essential for normal cell structure and for the formation of red blood cells. Research indicates that it may also have the power to boost immunity and slow the aging process.

Today, researchers know that vitamin A and carotenoid-rich sources are essential for proper vision. Vitamin A is also necessary, either directly or indirectly, to the proper function of nearly every organ in the body. In addition, it helps protect the integrity of the cells that line the body's interior and exterior surfaces, and it also appears to directly enhance immunity by boosting the production and improving the function of white blood cells.

When these three powerful vitamins interact with each other they create a powerful synergistic antioxidant effect which gives the body broad protection against damaging free radicals.

These minerals combine with certain enzymes to form our bodies' own defense of natural antioxidants. Thus, they 'up the ante' against free radicals, giving the body a double dose of antioxidant protection.

Besides their antioxidant effects, however, each mineral contributes to the overall health of the body. The eyes, skin, bones, liver, kidneys, and reproductive organs all depend on zinc for normal functioning, and though scientists are only beginning to realize the importance of selenium in human nutrition, it is known to protect red blood cells and cell membranes from damage as well as to work effectively with vitamin E. Copper helps deliver energy, while manganese is involved in bone development and protein metabolism.

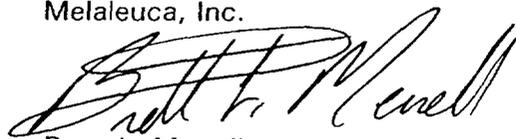
With the powerful antioxidant properties of Cell-Wise, you can protect yourself against the damaging effects of free radicals as well as maintain the healthy functioning of many body systems. Combined with a good diet and regular exercise, Cell-Wise can help guard your health and reduce your risk for degenerative conditions--providing protection that goes cell-deep.

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.



Brett L. Merrell
V.P. Product Marketing

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