



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

APR 14 1999 4 '99 APR 20 P2:13

Mr. McKay Christensen  
Chief Operating Officer  
Melaleuca, Inc.  
3910 South Yellowstone Highway  
Idaho Falls, Idaho 83402-6003

Dear Mr. Christensen:

This is in response to your letter of April 1, 1999 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 statement, among others, for the product Activate Immune Complex™:

“...enhances the activity of those cells which attack invading microbes”

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, mitigate, or cure diseases, 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-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 268

Page 2 - Mr. McKay Christensen

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)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

GCF-1 (Dorsey)

HFV-228 (SBenz)

HFV-232 (ABrown)

f/t:HFS-456:rjm:4/13/99:docname:64624.adv:disc37



Melaleuca, Inc.

3910 South Yellowstone Hwy  
Blaine Falls, Idaho 83402-6691  
208 522-6700

Legal Department  
Fax 208 528-2063

April 7, 1999

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

621-34  
4/12/99

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:

Need a wellness boost? Activate your defenses

Boosts your body's natural defenses to give you more fighting power

Helps maintain the strength of your white blood cells

Echinacea: In clinical studies, patients taking echinacea demonstrated stronger immune systems

Astragalus: Shown in studies to strengthen the antibody response

Arabinogalactan: A natural carbohydrate that enhances the activity of those cells which attack invading microbes

Vitamins C, E, and Folic Acid: Each contains strong immune-boosting properties

Adults and children: take at the first sign that the immune system needs help

These statements contain the statutory disclaimer. The name of the dietary supplement is Activate Immune Complex™, and the relevant dietary ingredients are Echinacea purpurea, Arabinogalactan, Astragalus membranaceus, Vitamin C, Vitamin E, Folic Acid, Zinc and Selenium.

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.

  
McKay Christensen  
Chief Operating Officer

MC/ds