



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT - 6 1999

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 September 27, 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 claims, among others, for the product "Activate Immune Complex":

"... get strong against germs. . ."

"... help rid your body of 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 statements that you are making for this product suggest that it is intended to treat, prevent, cure, or mitigate disease, namely illnesses caused by pathogenic microorganisms. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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,

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

975-0123

LET 306

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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, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0 163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-3 10 (BWilliams)

HFD-3 14 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

HFV-228 (Benz)

GCF- 1 (Barnett, Dorsey)

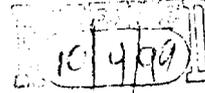
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Melaleuca, Inc.

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

September 27, 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

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:

- **Activate Immune Complex is a dietary supplement formulated to support your immune system. Three extracts--echinacea, astragalus and arabinogalactan--are included because they have been scientifically shown effective. For example, studies demonstrated that echinacea promotes the activity of natural killer cells--members of the immune system that help rid your body of foreign invaders.**
- **Other nutrients--vitamins E, C, folic acid, zinc and selenium--have also been found to be crucial to the development of white blood cells, which are prominent members of the immune system.**
- **Maintain your natural defenses, get strong against germs--and be there.**

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

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