



MAY 22 2000 12 84 '00 MAY 25 12:01

Kim Whitler
V.P. of Product Marketing
Melaleuca, Inc.
3910 South Yellowstone Highway
Idaho Falls, Idaho 83402-6003

Dear Mr. Whitler:

This is in response to your letter of May 9, 2000 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 product **PROVEXCV**:

“...keep your blood flowing smoothly through the arteries...”
“can help regulate platelet aggregation, thus helping to maintain normal circulation.”

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, or mitigate disease¹. 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-310, 7520 Standish Place, Rockville, Maryland 20855.

¹See the discussion on the claim “inhibits platelet aggregation” in paragraph 41 in the preamble to the final rule published in the January 6, 2000 Federal Register (65 FR 1000 at 1016).

975-0163

LET 367

Page 2 - Mr. Kim Whitler

Please contact us if you require 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

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-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Barnett, Nickerson)
f/t:HFS-811:rjm:5/19/00:docname70773.adv:disc47



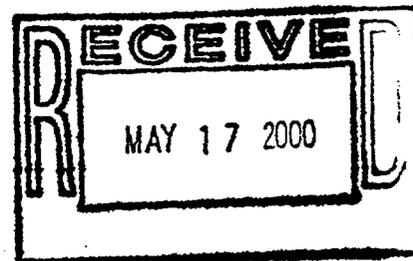
Melaleuca, Inc.

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

May 9, 2000

70 773

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:

- PROVEXCV helps protect your heart in two ways: 1) First, by providing powerful antioxidant protection for the cardiovascular system. 2) Second, by helping to keep your blood flowing smoothly through the arteries. How? Certain flavonoids found in PROVEXCV can help regulate platelet aggregation, thus helping to maintain normal circulation.
- In controlled human studies, university scientists administered PROVEXCV to subjects and discovered that it was significantly effective in naturally maintaining a healthy heart. Successive studies continue to reveal the promise of PROVEXCV as the cardio-care supplement of the future.
- Revolutionary protection for your heart.

These statements contain the statutory disclaimer. The name of the dietary supplement is PROVEXCV™, and the relevant dietary ingredients are grape seed extract, ginkgo biloba extract, bilberry extract, grape skin extract, quercitin powder, and fungal and plant proteases.

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.

Kim Whitler
V.P. of Product Marketing