



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUL 31 2000

Rec'd
AUG 11 2000
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Mr. Kim Whitler
V.P. 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 claims, among others, for the product EstrAval™:

“...maintain normal cholesterol levels and blood pressure...”

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 diseases, namely, hypercholesterolemia hypertension. This claim does 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.

975-0163
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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

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-800 (r/f, file)
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Nickerson)
f/t:HFS-811:rjm:7/31/00:docname:71476.adv:disc49



Melaleuca, Inc.

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

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May 9, 2000

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:

- Helps reduce the occurrence of hot flashes.
- A recent study showed that taking soy protein supplements (20 grams daily) helped women maintain normal cholesterol levels and blood pressure, while also significantly improving symptoms such as hot flashes.

These statements contain the statutory disclaimer. The name of the dietary supplement is EstrAval™, and the relevant dietary ingredients are Soy extract, Black Cohosh extract and Dong Quai extract.

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. Product Marketing