



FEB 27 1998

Food and Drug Administration  
Washington, DC 20204

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

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FEB 17 1998

FEB 19 1998

Dear Mr. Merrell:

This is in response to your letter of February 5, 1998 to the Food and Drug Administration (FDA) pursuant to 21 USC 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 statements, among others, for the product "ProstAvan:"

"...helping to restore and maintain proper urinary flow in men."

"In fact, 90% of German citizens experiencing troublesome prostate symptoms are advised by their physicians to use saw palmetto berry and other plant extracts to relieve those symptoms."

"For example, in one particular European study, 110 patients with prostate and urinary difficulties took 320 mg of saw palmetto berry or a placebo for 28 days. Those who used saw palmetto experienced a positive effect on urinary function."

21 USC 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 claims that you are making for this product suggest that it is intended to treat, prevent, or mitigate disease, in that it is intended to treat, prevent, or mitigate benign prostatic hypertrophy. These claims do not meet the requirements of 21 USC 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 USC 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 yours,

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

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