



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

AUG - 9 2000

Rec'd
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Tyrie A. Barrott, Esq.
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Melaleuca, Inc.
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Dear Ms. Barrott:

This is in response to your letter to the Food and Drug Administration (FDA) dated June 20, 2000. In your letter, you stated that Melaleuca, Inc. disagreed with our assertion that certain claims cited in our letter dated May 22, 2000 were disease claims that suggested that the product PROVEXCV was a drug under the Federal Food, Drug, and Cosmetic Act (the Act).

In our May 22, 2000 letter, we stated that the claims "...keep your blood flowing smoothly through the arteries..." and "can help regulate platelet aggregation, thus helping to maintain normal circulation" suggest that the product PROVEXCV is intended to treat, prevent, or mitigate disease. In your letter you stated that you disagree with our assertion that the claim about regulating platelet aggregation is a disease claim. You further stated that while you are aware of the language in the preamble to the January 6, 2000 final rule on structure/function claims that discusses platelet aggregation claims, you believe that the position articulated by the agency is misguided and that such claims are indeed appropriate structure/function claims under the Act.

We disagree. As we stated in the preamble to the final rule, although platelet aggregation is a normal function needed to maintain homeostasis, inhibiting or decreasing platelet aggregation is a well-recognized therapy for the prevention of stroke and recurrent heart attack (65 FR 1016). External intervention to affect platelet aggregation is not necessary except in conditions where an underlying disease calls for intervention. In fact, absent a need to alter platelet aggregation, intervention to increase or decrease it may result in untoward effects, such as increased clotting or bleeding. Consequently, any claim that a product affects platelet aggregation would appear to implicitly represent the product as being necessary to correct some deviation in platelet function from the normal. For this reason, we are not persuaded that the position articulated in the January 6, 2000 preamble is incorrect and we still believe that the claim proposed in your original submission is a disease claim.

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Nonetheless, as we stated in the January 6, 2000 preamble, platelet aggregation per se is a normal function of the body. Elsewhere in the preamble, we stated that the use of terms such as "stimulate," "maintain," "support," "regulate," or "promote" can be appropriate when the statements do not suggest disease prevention or treatment or use for a serious health condition that is beyond the ability of the consumer to evaluate (65 FR 1018). Therefore, if a claim about platelet aggregation does not imply disease prevention, treatment, or mitigation, it may be an appropriate structure/function claim. A claim that a product is important or plays a role in the maintenance or regulation of platelet aggregation or function that is already normal or within normal limits might be an appropriate structure/function claim depending on the context. The use of this type of clarifying phrase to avoid the implicit disease association of the original claim is similar to that which the agency indicated would be appropriate for claims such as cholesterol claims (see 65 FR 1018).

You also state in your letter that you believe that the claim "...keep blood flowing smoothly through the arteries..." is an appropriate structure/function claim that does not imply disease treatment, prevention, or mitigation because smooth blood flow is a normal, healthy function of the body. We disagree. We believe that any claim about a product affecting blood flow is an implied disease claim. While blood flow is a normal function of the body, a claim about external intervention to affect blood flow is implicitly a claim to correct a defect in blood circulation because it is not necessary to improve, modify, or otherwise affect blood flow unless it is impaired. As discussed above (for platelet aggregation claims), a claim that a product is important or plays a role in the maintenance or regulation of blood flow that is already normal or within normal limits could be an appropriate structure/function claim, depending on the context.

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, Compliance Branch, HFR-PA340



Melaleuca, Inc.

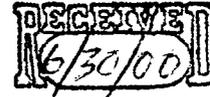
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June 20, 2000

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John B. Foret
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Washington, D.C. 20204



Dear Mr. Foret:

This is in response to your letter of May 22, 2000 to Kim Whitler in connection with our 403(r)(6) notice for the product PROVEXCV. Melaleuca acknowledges FDA's concerns but respectfully disagrees with the agency's position that the subject structure/function claims suggest our product is intended to treat, prevent or mitigate disease.

While Melaleuca is fully aware of the preamble and the final rule concerning structure/function claims, we do not believe it prohibits the submitted claims. The preamble language specifically focuses on the "inhibition" or "reduction" of platelet aggregation, not the "regulation" of platelet aggregation as our claim shows. Even so, Melaleuca argues that FDA's preamble comments regarding inhibiting and reducing platelet aggregation are misguided and such claims--in addition to regulation of platelet activity--are appropriate structure function claims under the Act.

If FDA continues its concerns with our submitted structure/function claim, we would be interested in knowing whether the claim "maintains normal platelet aggregation" or the claim "maintains healthy platelet aggregation" would be acceptable to the agency.

Melaleuca also disagrees with FDA's comments concerning the claim "... keep blood flowing smoothly through the arteries ...". It is well known that smooth blood flow is a normal, healthy "function" of the human body. The claim to maintain a smooth blood flow is an appropriate structure/function claim not implying disease treatment, prevention or mitigation.

Although we disagree with FDA's assessment of these claims, we do wish to cooperate in resolving the agency's concerns. Therefore, if FDA has additional comments or desires to further clarify its position in relation to these claims, please do not hesitate to contact me.

Very truly yours,

Tyrie A. Barrott
Assistant General Counsel