

# Procter & Gamble

The Procter & Gamble Company  
Winton Hill Technical Center  
6071 Center Hill Avenue, Cincinnati, Ohio 45224-1703

November 22, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Room 1061  
Parklawn Building  
5630 Fishers Lane  
Rockville, MD 20852  
(301) 827-6860

578  
00  
NOV 24  
A9:49

Re: *Plant Sterol/Stanol Esters and Coronary Heart Disease Claims*  
*Docket Nos. 00P-1275 and 00P-1276*  
*65 Fed. Reg. 54685 (September 8, 2000)*

The Procter & Gamble Company submits the following comments in response to the above listed interim final rule allowing a health claim for foods containing sterol or stanol esters. Procter & Gamble (P&G) is a manufacturer of a wide variety of consumer products, including foods and beverages, and as such has significant interest in the ability to use health claims for those products.

P&G supports FDA's decision to permit claims on food labels and labeling concerning the role of plant sterol/stanol esters (plant esters) in the prevention of coronary heart disease, however, the capability of making this claim should be extended to similar foods that have similar dietary profiles and deliver required sterol/stanol ester levels for efficacy. The health claim should not be restricted to a limited set of food where other foods with similar profiles could result in similar benefit to consumers.

Therefore, this comment requests FDA to extend the exemption from disqualifying regulations (low fat criteria and jelly bean rule) in the interim final rule beyond the currently specified spreads and dressings for salad to encompass other foods having similar dietary profiles that could also be good future vehicles for delivering this technology. As the regulation is currently written, closely related foods (one example is vegetable oils used in cooking or to make home made salad dressings) that have similar dietary profiles (total fat, saturated fat, calories) to the exempted foods would currently be prohibited from carrying the health claim. Some of these foods would be excellent fat based vehicles to deliver the sterol/stanol ester technology.

00P-1275

C 9

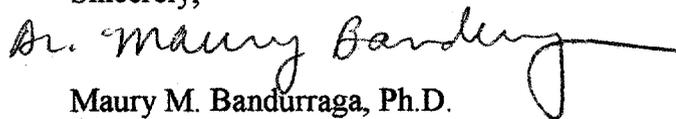
*Procter&Gamble*

We believe it would create significant consumer confusion if a food with a similar dietary profile to the exempted food in the interim final rule also contains the required amount of sterol/stanol esters but could NOT make the health claim is located on the shelf next to a food with similar profile, with the claim. This alternate food should similarly be exempt from the disqualifiers and be able to make the health claim as long as:

- 1) the food does not exceed the dietary profile of foods approved in this health claim,
- 2) the same efficacious level of sterol/stanol esters per serving is present, and
- 3) the food components and labeling meet all other FDA safety and regulatory standards (including GRAS determination where needed) .

In summary, P&G appreciates the opportunity to comment before the interim rule is final, and urges FDA to allow foods with similar nutritional profiles and required levels of sterol/stanol esters to make the same types of health claims, by extending the disqualifying criteria allowed in the interim final rule to other foods that meet other regulatory requirements.

Sincerely,



Maury M. Bandurraga, Ph.D.

Regulatory Affairs Manager

Professional and Regulatory Services

Food and Beverage Research and Development

The Procter & Gamble Company

(513) 634-4137 phone, (513) 634-1813 fax