U. S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Premarket Approval

Agency Response Letter
GRAS Notice No. GRN 000053

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

December 20, 2000

Maury M. Bandurraga, Ph.D.
The Procter & Gamble Company
Winton Hill Technical Center
6071 Center Hill Avenue
Cincinnati, OH 45224

Re: GRAS Notice No. GRN 000053

Dear Dr. Bandurraga:

The Food and Drug Administration (FDA) is responding to the notice, dated July 17, 2000, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received the notice on July 24, 2000 and designated it as GRAS Notice No. GRN 000053.

The subject of your notice is phytosterol esters. The notice informs FDA of the view of The Procter & Gamble Company (P&G) that phytosterol esters are GRAS, through scientific procedures, for use as an ingredient in vegetable oil, at a level up to 13.3 per cent by weight, for home use applications such as baking, frying, and salad dressings.

You obtain the phytosterol esters from Cargill, who submitted a GRAS notice for its ingredient in June, 2000 (GRN 000048). Your notice describes the identity and composition of the ingredient produced by Cargill. Your notice includes food grade specifications for phytosterol esters, including a specification for lead of less than 0.1 milligrams/kilogram.

The major components of phytosterol esters are beta-sitosterol, campesterol, and stigmasterol. These components already are present in currently marketed ingredients. These products include "vegetable oil sterol esters," which are marketed by Lipton in Take Control™ brand spread, "plant stanol esters," which are marketed by McNeil Consumer Healthcare in Benecol™ brand spread, and "tall oil

phytosterols" which are marketed by Novartis Consumer Health, Inc. in Phytrol™ brand spread. FDA had previously evaluated these ingredients when consumed in spread (Refs. 1 through 3). Consumption would be approximately 3 grams of plant sterols or plant stanols per person per day (which is equivalent to approximately 5 grams of plant sterol esters or plant stanol esters per person per day) when following specific label directions recommending consumption of multiple servings per day of the spread. You estimate that the expected additional consumption of phytosterol esters, at the 90th percentile level, from your proposed use in vegetable oil would range from approximately 750 milligrams per person per day to approximately 2100 milligrams per person per day.

Your notice describes an unpublished study demonstrating the stability of phytosterols during typical home cooking conditions. You conclude that no significant new oxidized species were formed by heating the vegetable oil containing phytosterol esters compared to standard vegetable oil. Your notice also describes a series of published studies conducted with free phytosterol, vegetable oil sterol esters, plant stanol esters, or tall oil phytosterols. Because evaluation that a use of a food ingredient is safe is a time-dependent judgment, you mention that P&G plans, as for any new product, to conduct the firm's usual post-market evaluation of consumer acceptance and use for this new product and to share with FDA any information on product usage and exposure that materially changes the GRAS determination presented in your notice.

Your notice includes the findings of a panel of individuals (P&G's GRAS panel) who evaluated the data and information that are the basis for P&G's GRAS determination. P&G considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. In its report, P&G's GRAS panel concludes that the composition of the ingredient that P&G would add to vegetable oil is equivalent to the ingredient "vegetable oil sterol esters" that is marketed by Lipton in its Take Control™ brand of vegetable spread. In its report, P&G's GRAS panel considered additional phytosterol intake from the consumption of P&G's vegetable oil product compared to the consumption of phytosterol esters contained in currently available spreads and assessed phytosterol stability during typical home cooking conditions.

Based on the information provided by P&G, as well as other information available to FDA, the agency has no questions at this time regarding P&G's conclusion that phytosterol esters are GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of phytosterol esters. As always, it is P&G's continuing responsibility to ensure that food ingredients that P&G markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the Office of Premarket Approval's homepage on the Internet (at http://vm.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,
/s/
Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and Applied Nutrition

References

1. Letter dated April 30, 1999, from Alan Rulis of FDA to Daniel R. Dwyer.

2. Letter dated May 17, 1999, from Alan Rulis of FDA to Vivian A. Chester and Edward B. Nelson.

3. Letter dated April 24, 2000, from Alan Rulis of FDA to Judith A. Weinstein.

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