

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
February 4, 2003

Agency Response Letter GRAS Notice No. GRN 000112

C. K. Gund, Ph.D.
Phoenix Regulatory Associates
21525 Ridgetop Circle, Suite 240
Sterling, VA 20166

Re: GRAS Notice No. GRN 000112

Dear Dr. Gund:

The Food and Drug Administration (FDA) is responding to the notice, dated August 15, 2002, that you submitted on behalf of Teriaka Ltd. (Teriaka) 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); the GRAS proposal). FDA received the notice on August 19, 2002, filed it on August 19, 2002, and designated it as GRAS Notice No. GRN 000112.

The subject of the notice is phytosterols. The phytosterols would be added to food as a component of a fatty mixture (either a vegetable fat mixture, a vegetable oil mixture, or an anhydrous milk fat mixture). The notice informs FDA of the view of Teriaka that phytosterols are GRAS, through scientific procedures, for use as an ingredient in margarine and vegetable-based spreads (margarine-like); yogurt and yogurt-like products; milk-based juice beverages; ice cream and non-standardized ice cream products; cream cheese and cream cheese-like products; snack bars (health bars); salad dressing, mayonnaise, French dressing, and dressings for salads; and white breads, white rolls and buns, and comparable non-standardized white bread products.

Teriaka describes the products it manufactures containing phytosterols as vegetable fat mixtures with phytosterols, vegetable oil mixtures with phytosterols, or anhydrous milk fat mixtures with phytosterols, depending on the fat used to produce the sterol-enriched ingredient. The phytosterols that Teriaka uses are either from vegetable oils (soybean, cottonseed, corn, sunflower seed, canola, or peanut) or tall oil extracted from pine trees (*Pinus pinaster* and *Pinus sylvestris*). Teriaka notes that the vegetable oil phytosterols that it processes into a fatty mixture are the subject of a previous GRAS notice, i.e., GRN 000061. Teriaka notes that the tall oil phytosterols that it processes into a fatty mixture predominantly contain beta-sitosterol, beta-sitostanol, campesterol, and campestanol and compares the composition of these tall oil phytosterols with that of the tall oil phytosterols that are the subject of a previous GRAS notice, i.e., GRN 000039.

Teriaka describes the manufacture of the tall oil phytosterols that it processes into a fatty mixture. Phytosterols are produced from raw tall oil pitch, which is produced from pine trees as a by-product of the kraft pulping process and is composed of the neutral non-lignin, non-cellulosic portion of the pine

trees. The raw tall oil pitch is distilled to give fatty acids, rosin acids, and tall oil pitch. The tall oil pitch is then extracted with alcohol and heated to give primary phytosterol crystals. After cooling, these crystals are washed with water and filtered to separate them from the tall oil residues. The phytosterols are recrystallized, filtered, dried under vacuum, and then milled and sieved to obtain the required crystal size. Teriaka provides specifications for the tall oil phytosterols and for the fatty mixtures that contain phytosterols. Teriaka estimates that per capita intake of phytosterols from use in fatty mixtures would be 1.6 grams per person per day (g/p/d) at the mean and 3.6 g/p/d at the 90th percentile.⁽¹⁾

In its notice, Teriaka discusses published studies addressing the safety of acute, sub-chronic, and chronic intakes of phytosterols and the potential for genotoxic, reproductive, or developmental effects of phytosterols. Teriaka also discusses published studies addressing the metabolism of plant sterols in animals, the effect of phytosterols on sex hormones in animals and humans, the effect of phytosterols on fat soluble vitamins and carotenoids, and the safety of the cumulative intake of plant sterols. Teriaka notes that most of these studies were discussed in previous GRAS notices and Food Master Files submitted to FDA by other manufacturers (i.e., GRN 000039, GRN 000048, GRN 000053, GRN 000061, FMF 000625, and FMF 000626). Teriaka concludes that its ingredients containing either vegetable or tall oil phytosterols are safe for their intended use.

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

In the notice, Teriaka states its intention to use phytosterols in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity. If you have any questions about the use of phytosterols in standardized foods that would be marketed in the United States, you should contact the staff in Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS), Division of Standards and Labeling Regulations, HFS-820, 5100 Paint Branch Parkway, College Park, MD 20740. You can reach this division by telephone at (301) 436-2375. The Office of Food Additive Safety (OFAS) neither consulted with ONPLDS on the use of phytosterols in standardized foods nor evaluated the information in your notice to determine whether your use of phytosterols is permitted by the applicable standards of identity.

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 homepage of the Office of Food Additive Safety (on the Internet at <http://www.cfsan.fda.gov/~lrd/foodadd.html>).

Sincerely,

/s/

Alan M. Rulis, Ph.D.

Director

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition

(1)FDA normally considers exposure to an ingredient only for eaters of foods containing the ingredient. For these phytosterols, the per capita intake estimated by Teriaka is comparable to the "eaters only" intake estimated by FDA.

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