

Sheryl A. Marcouiller Senior Food Law Counsel Kraft Foods North America, Inc.

mailto:Julie.Schrimpf@cfsan.fda.gov

Julie Schrimpf, PhD, RD
Division of Nutrition Programs and Labeling
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Harvey W. Wiley Federal Building
5100 Paint Branch Pkwy (HFS-830)
College Park, MD 20740-3835

Dear Ms. Schrimpf:

On August 8th, Kraft Foods North America, Inc. (Kraft) notified the Food and Drug Administration (FDA) that the company plans to use the food label to educate consumers about the well-established relationship between the consumption of whole grain foods and reduced risk of coronary heart disease. As required by section 403(r) (3)(C) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 343(r)3)(C), Kraft provided to FDA the authoritative statement of the Food and Nutrition Board of the National Research Council upon which the label claim will be based, along with additional detailed supporting scientific literature. FDA subsequently advised Kraft that the required notice was received on August 11th and the notification period would expire on December 9th. With this letter, we are including a petition revised to incorporate recent discussions with FDA, as confirmed in my letter dated November 3rd and in response to your subsequent request for a fully amended petition to facilitate display on the agency's web site.

November 26, 2003

The exact wording of the claim will be as follows: "Diets rich in whole grain foods and other plant foods, and low in saturated fat and cholesterol, may reduce the risk of heart disease." The claim will be used on foods that contain at least 51% whole grain (using dietary fiber as a marker); meet the regulatory definitions for "low saturated fat" and "low cholesterol"; bear quantitative trans fat labeling; contain less than 6.5 grams total fat and less than or equal to 0.5 grams trans fat per reference amount customarily consumed (following standard rounding rules); and meet all general requirements for health claims in 21 C.F.R. 101.14.

Respectfully submitted,

Sheryl A. Marcouiller

Senior Food Law Counsel

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