



Kraft Foods

8784 '03 DEC -4 19:51

Sheryl A. Marcouiller
Senior Food Law Counsel

Julie.Schrimpf@cfsan.fda.gov

November 3, 2003

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:

Last August, 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 (FFDCA), 21 U.S.C. § 343(r)(3)(C), Kraft provided to FDA the authoritative statement of the Food and Nutrition Board (FNB) of the National Research Council (NRC) 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. This letter amends the company's notification consistent with our recent discussion, but with the understanding that the 120-day notification period still will expire on December 9, 2003.

The exact wording of the proposed claim is as follows: "Diets rich in whole grain foods and other plant foods, and low in saturated fat and cholesterol, may help reduce the risk of heart disease." The claim will be used on foods that contain a minimum of 51% whole grains (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 0.5 grams or less 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.

Thank you for your consideration.

Sincerely,

Sheryl A. Marcouiller
Senior Food Law Counsel

2003Q-0547

LETA