



November 10, 2006

Essie Yamini, PhD, RD
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Re: Health Claim Notification

Dear Dr. Yamini:

Last July, Kraft Foods Global, Inc. (Kraft) notified the Food and Drug Administration (FDA) of plans to use the food label to educate consumers about the relationship between reduced risk of heart disease and diets low in saturated fat, trans fat, and cholesterol. This letter amends our notification consistent with our recent discussion, but with the understanding that the 120-day notification period will still expire on November 15, 2006. This amendment substitutes the claim language, trans fat criteria, and authoritative statement described below for the corresponding items described in the Health Claim Notification.

The exact wording of the claim is "Diets low in saturated fat and cholesterol, and as low as possible in trans fat, may reduce the risk of heart disease." This claim may appear on foods that contain less than 0.5 grams of trans fat per reference amount customarily consumed (RACC) and meet other criteria outlined in the Notification.

The authoritative statement for this claim is the *2005 Dietary Guidelines for Americans*. In the Executive Summary and Key Recommendations, the *Dietary Guidelines* advise that Americans should consume less than 10% of calories from saturated fatty acids and less than 300 mg/day of cholesterol, and keep trans fatty acid consumption as low as possible. The *Guidelines* also recommend that total fat intake be kept between 20 to 35 percent of calories, with most fats coming from sources of polyunsaturated and monounsaturated fatty acids, such as fish, nuts, and vegetable oils. In the Overview to the Fats chapter, the *Guidelines* state that "[h]igh intake of saturated fats, trans fats, and cholesterol increases the risk of unhealthy blood lipid levels, which, in turn, may increase the risk of coronary heart disease." Copies of the pages containing these statements are attached.

Although Kraft is identifying the *2005 Dietary Guidelines for Americans* as the authoritative statement for the planned claim, Kraft also believes that the Adult Treatment Panel III (ATP III)

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report,¹ described in our original Notification, qualifies as an authoritative statement of the National Cholesterol Education Program, the National Heart, Lung, and Blood Institute, and the National Institutes of Health. We would welcome the opportunity to discuss the authoritative nature of this report with the agency further, should that issue arise in the future.

Thank you for your consideration of this amendment.

Sincerely,



Andrea M. Bruce
Senior Counsel, Food Law
Kraft Foods Global, Inc.

¹ Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) (NIH Pub. No. 02-5215) (Sept. 2002).