DEPARTMENT OF HEALTH AND HUMAN SERVICES



Public Health Service

Food and Drug Administration College Park, MD 20740

AUG 19 2003

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Jean E. Spence Senior Vice President Research and Development Kraft Foods North America, Inc. Northfield, Illinois 60093-2753

Re: Notification for Health Claim Based on an Authoritative Statement: Whole Grain Foods and Heart Disease

Dear Ms. Spence:

This letter acknowledges receipt on August 11, 2003 by the Food and Drug Administration (FDA) of the health claim notification you submitted pursuant to Section 403(r)(3)(C) of the Federal Food Drug and Cosmetic Act (FFD&C Act)(21 U.S.C. § 343(r)(3)(C)). The notification is informing FDA that Kraft intends to make a health claim based upon an authoritative statement of the Food and Nutrition Board (FNB). The exact wording of your proposed claim is: "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."

This notification is undergoing FDA review. In accordance with Section 403(r)(3)(C) of the FFD&C Act, within 120 days (ending on December 9, 2003) of receipt of your health claim notification, you will be informed by FDA if the notification does not comply with Sections 403(r)(2) and (3) of the FFD&C Act. A lack of action by FDA within the 120-day period will deem the proposed health claim approved and will allow a food with a label containing the claim to be introduced into interstate commerce.

Please feel free to contact me at 301-436-2031 if you have questions concerning this notification.

Sincerely yours,

Julii Schumpf

Julie E. Schrimpf, Ph.D., R.D. Office of Nutritional Products, Labeling and Dietary Supplements Center for Food Safety and Applied Nutrition

20030-0547

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