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Division of Nutrition Programs and Labeling
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

**Re: Nutrient Content Claims Petition
Total Carbohydrate Content of Foods**

Dear Sir or Madam:

Kraft Foods North America, Inc. (Kraft) respectfully submits the attached Petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (FFDCA). Kraft seeks a regulation governing nutrient content claims for the “total carbohydrate” content of foods. Specifically, Kraft asks the Food and Drug Administration (FDA or the agency) to propose rules for the following claims: carbohydrate free, low carbohydrate, reduced carbohydrate, less carbohydrate, good source of carbohydrate, and excellent source of carbohydrate. In seeking definitions for carbohydrate nutrient content claims, Kraft does not intend to imply that carbohydrate management is preferred to any other scientifically sound dietary approach. Instead, Kraft seeks to foster the use of FDA defined nutrient content claims consistent with the requirements of the Nutrition Labeling and Education Act.

The cacophony of unapproved carbohydrate claims proliferating throughout American grocery stores at an explosive rate provides strong evidence that FDA should initiate rulemaking on an expedited basis. As explained in the Petition, market research done by Kraft indicates that consumers lack reliable information about the range of carbohydrate content that may be consumed consistent with current dietary recommendations. To develop and maintain health dietary practices, consumers need to understand the scientifically sound recommendations issued by the National Academy of Sciences, Institute of Medicine in *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*, at 11-1 (2002) (the “Macronutrient Report”). Rules for nutrient content claims reflecting those recommendations would guide consumers and at the same time promote fair competition consistent with public health goals.

The definitions recommended in the Petition are based upon the analysis FDA used to define the nutrient content claims that are allowed today. The suggested rules also have been examined carefully for consistency with the latest dietary advice

from public health experts. Additionally, the reasoning underlying the recommendations is set forth in detail to facilitate the agency's review and public comment.

To Kraft, the need for agency action appears so acute that FDA should consider using the authority Congress granted in section 403(r)(7) to expedite the rulemaking process by adopting interim final rules. As FDA noted in the Advance Notice of Proposed Rulemaking published November 25, 2003, Congress authorized the agency to adopt interim final rules in response to petitions submitted under section 403(r). It is appropriate for FDA to do so in this case because consumers need reliable information to develop and maintain health dietary practices. Alternatively, Kraft seeks guidance from FDA indicating that enforcement discretion will be exercised to allow claims consistent with this Petition on an interim basis as the rulemaking process evolves; provided, of course, that the label as a whole is not false or misleading. Ample precedent supports the use of interim guidance when rapid evolution of the regulatory framework is in the best interests of consumers.¹

All of the information required by 21 C.F.R. § 101.69 is included in the Petition. We have enclosed two copies printed on paper. For convenience, we also have enclosed a compact disc with adobe (.pdf) files of this cover letter, the Petition, and referenced materials. Thank you for your consideration.

Yours very truly,



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¹ See, e.g., 47 Fed. Reg. 26580, 86 (proposing defined sodium content claims and issuing guidance regarding the use of comparative claims); 51 Fed. Reg. 42584, 89 (proposing defined cholesterol content claims and announcing "no objection if manufacturers label food truthfully to show comparative cholesterol reductions using such other terms as less cholesterol or lowered cholesterol"). Interim guidance is also consistent with the commercial speech protection of the First Amendment and the mandate of recent cases such as *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), and *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002).