



Kraft Foods

Sheryl A. Marcouiller  
Senior Food Law Counsel

July 26, 2004

**VIA AIRBORNE EXPRESS**

Robert E. Brackett, Ph. D.  
Director, Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, Maryland 20740-3835

Re: Nutrient Content Claims Petition—Total Carbohydrate Content of Foods  
Docket No. 2004P-0105

Dear Dr. Brackett:

Kraft Foods agrees to an extension of time until October 31, 2004 for the Food and Drug Administration to respond to our petition seeking regulations defining nutrient content claims for the carbohydrate content of foods. We understand that the agency will make a good faith effort to publish a Notice of Proposed Rulemaking by that date and also that FDA will attempt to promulgate a Final Rule within the time frame prescribed by regulation, that is, by next May. We acknowledge that timing of the Final Rule will depend in part upon the comments submitted in response to the initial proposal.

To help ensure that the agency's resources are focused on the most important regulations, we are prepared to withdraw the part of our petition that seeks a rule governing "good source" and "excellent source" of carbohydrate claims, should it prove unrealistic to deal with the issues those claims present on the same schedule. Our key goal is to expedite the time when industry will be able to use the FDA defined nutrient content claims "low carbohydrate," "carbohydrate free," "reduced carbohydrate," and "less carbohydrate" consistent with the requirements of the Nutrition Labeling and Education Act, as those are the claims in which consumers are most interested at this time.

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In our petition, we asked FDA to consider issuing an Interim Final Rule because we are convinced that consumers need reliable information about the carbohydrate content of foods to develop and maintain healthy dietary practices. Alternatively, we asked FDA to indicate that enforcement discretion will be exercised to allow claims consistent with the Proposed Rule on an interim basis as the rulemaking process evolves. When rapid evolution of the regulatory framework is in the best interests of consumers, as is the case here, ample precedent supports the use of interim enforcement discretion.<sup>1</sup> We understand that FDA will consider providing such guidance in the preamble to the Proposed Rule.

Our petition does not seek publication of a regulation governing the use of terms such as "net carbohydrate," but we agree with others who have suggested that it would be helpful for FDA to provide guidance on the use of such terminology. Therefore, we suggest FDA document, in the preamble to the Proposed Rule, the agency policy that such terminology may be used as long as the label is not false or misleading.

Thank you for your consideration. Please do not hesitate to contact me if you have questions.

Sincerely,



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

cc: Heather D. Bañuelos

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<sup>1</sup> 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 (proposed 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).