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Sent: Tuesday, June 07, 2005 6:58 PM  
To: Dockets, FDA  
Cc: Yehling, Barbara  
Subject: Docket No. 2005N-0120

We have attached the comments of Kraft Foods Global, Inc.

<<Carb Comments.pdf>>

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June 7, 2005

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BY ELECTRONIC MAIL

Division of Dockets Management  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, Maryland 20852

Re: **Docket No. 2005N-0120**; Agency Information Collection Activities; A Proposed Collection; Comment Request; Experimental Study of Carbohydrate Content Claims on Food Labels; 70 Fed. Reg. 18032 (Apr. 8, 2005)

Dear Sir or Madam:

Kraft Foods Global, Inc. (Kraft) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) plans to conduct a study assessing consumer understanding of carbohydrate content claims. Kraft is a \$30 billion global company, the largest food manufacturer in North America, and the second largest worldwide. For over 100 years, Americans have trusted the well-known brands Kraft sells. Today, Kraft brands are found in more than 99% of all U.S. households.

Kraft is among the petitioners who have asked FDA to establish science-based carbohydrate nutrient content claims; and, accordingly, we have a substantial interest in ensuring that FDA adopts appropriate rules in a timely manner. Historically, FDA rules for nutrient content claims have followed closely the statutory provisions Congress adopted in the Nutrition Labeling and Education Act of 1990 (NLEA). In short, the rules are based on comparing the level of a nutrient in a food to a science-based reference intake or clearly identified reference food. Consequently, while excellent consumer research skills are at the core of our business competencies, to us the role of such research in the context of a proceeding to define science-based nutrient content claims is at best unclear.

In the spirit of making the proposed research more productive, we offer the following suggested modifications to improve the quality of the information generated by the study.

- First, we suggest that the study's focus on both explicit and implied messages be narrowed to better reflect the legal framework under which FDA regulates nutrient content claims. For example, the study evidently would examine whether claims such as "low carbohydrate" may convey some implied meaning to consumers beyond the food's carbohydrate content. This line of inquiry seems inconsistent with FDA's longstanding regulation of nutrient content claims as direct objective statements about the level of a particular nutrient in food relative to an authoritative reference value for that nutrient.
- Second, we recommend making the precise objectives and decision criteria of the study more clear prior to fielding. This process facilitates assessment of the study design, promoting enhancements and appropriate use of data upon completion.
- Third, we recommend that consumers be asked to evaluate all claims within the context of the Nutrition Facts to more closely approximate real-life conditions.

In summary, Kraft asks FDA to revise the study to better reflect the agency's legal authority, regulatory precedent, and sound research practices. The basis for these suggested modifications is described more fully below.

**I. Modify the Study Design to Better Reflect the Legal Framework for FDA's Regulation of Nutrient Content Claims**

According to the Federal Register notice, the proposed study is intended to enhance FDA's understanding of consumer response to carbohydrate claims on food labels. To accomplish this objective, FDA proposes to examine whether a variety of carbohydrate claims (e.g., "low carb," "x g net carbs," "carbconscious") convey certain implied messages to consumers. For example, the proposed study will examine whether the carbohydrate claims suggest that a food is 1) "healthier" or otherwise more desirable or 2) "lower" or "higher" in total carbohydrate, calories, and other nutrients than the same product without the claim or with a different claim.

To us, these lines of inquiry seem inconsistent with the legal framework for FDA's regulation of nutrient content claims. NLEA created detailed requirements for the regulation of nutrition and health-related claims, including nutrient content claims such as "low carbohydrate." By law, "nutrient content claims" are claims that characterize the

level of a nutrient in food by suggesting that the nutrient is absent or is present in a nutritionally significant amount—in other words, that the food contains “a little” or “a lot” of the nutrient as compared to an authoritative reference value or reference food. Nutrient content claims may be express, and include absolute (e.g., “low fat”) and relative (e.g., “reduced fat”) claims. Nutrient content claims may also be implied (e.g., “healthy”).

Consistent with the NLEA framework, FDA has historically regulated absolute and relative content claims as direct statements about the levels of specific nutrients, and as distinct from each other and from implied claims. This point of view is evident in the separate regulations and unique definitions FDA established for absolute, relative, and implied nutrient content claims. In establishing definitions for absolute and relative nutrient content claims, the agency evaluated each nutrient on its own merits and in light of its science-based reference intake. In defining implied claims such as “healthy,” which obviously convey varied and more complex messages, FDA has appropriately relied on definitions for certain absolute claims, such as “low saturated fat.”

The NLEA framework for nutrient content claims is sound because it accounts for the complexity and variation of everyday diets. Consumers may seek foods with a specific nutrient profile (e.g., “low fat,” “high fiber,” “good source of calcium,” “high protein”) for a myriad of reasons unrelated to other product attributes, including the overall “healthiness” of a food. For instance, an individual with chronically low calcium intakes may be in a good position to consume increased amounts of cheese as a source of calcium, and may do so as part of an overall healthful diet; a person seeking fiber might benefit from consuming a fiber-rich food such as popcorn, even if the popcorn consumed is not “healthy” as defined by FDA. Similarly, a person seeking a cookie as a treat can benefit from choosing a low or reduced fat cookie, even though that cookie is not intended to meet basic nutrition needs in the way that other products might.

It is important as a matter of law and sound nutrition policy that express nutrient content claims and implied claims such as “healthy” be regulated under the distinct criteria and frameworks that FDA has long applied, and not be confused, even in the context of consumer research. An inquiry as to whether express nutrient content claims convey overall product healthfulness or other implied messages is no more appropriate for carbohydrate claims than it was for fat, sodium, or other claims evaluated by FDA. Moreover, to the extent that the effect of a claim on consumer understanding of a product’s healthfulness is of concern, that concern is best addressed through the disclosure criteria applicable for all nutrient content claims.

**II. Clearly Identify Study Objectives and Decision Criteria**

In our experience, effective consumer research is designed with a clear objective and decision criteria in mind prior to fielding. This ensures that the study design will satisfy its intended purpose/objective by providing the appropriate information necessary to make the decision in question.<sup>1</sup> Given the cost and rigor of the proposed carbohydrate study, it is presumably intended to inform one or more specific decisions; yet, the study description provided in the Federal Register includes no discussion of decision criteria. We urge the agency to establish decision criteria (and publish them) before finalizing the design of this study.

**III. The Study Design Should Reflect Real-Life Conditions, Including Access to the Nutrition Facts Panel**

The proposed design calls for evaluation of consumer responses to carbohydrate claims presented with and without access to the Nutrition Facts, yet consumers will always have nutrition labeling available when they encounter carbohydrate label claims in the marketplace. We suggest that the agency conform the test to real life conditions and limit evaluation of consumer responses to scenarios where the nutrition information is available.

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In summary, Kraft requests that FDA carefully reevaluate the study design and modify it as described above to better reflect the agency's legal authority, regulatory precedent, and sound research practices.

Respectfully submitted,

Barbara Yehling



Sheryl A. Marcouiller

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<sup>1</sup> See David Aaker. Marketing Research. New York: John Wiley and Sons, Inc., 1995 ("In general, if research is not going to have an effect on decisions, it is an exercise in futility.") Aaker advocates clarifying upfront what research can accomplish by assessing (1) the various actions under consideration and (2) precise steps that may be taken, given the feasible outcomes of the research.

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