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Division of Dockets Management  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Docket No. 2003N-0496, Food Labeling: Health Claims and Dietary Guidance**

Kellogg Company ("Kellogg") welcomes this opportunity to provide comments in response to the advance notice of proposed rulemaking ("ANPR") regarding the use of health claims and dietary guidance statements in the labeling of conventional human foods and dietary supplements. The interim policies, once finalized, will improve consumer access to health information and promote competition among food companies based upon the health-related properties of foods. Kellogg applauds the Food and Drug Administration ("FDA") for moving toward the goal of establishing by regulation specific procedures and standards whereby qualified health claims will be permitted. We also concur with FDA's view that dietary guidance, as envisioned by the agency, will provide valuable information to consumers.

Throughout its 98-year history, Kellogg has remained committed to the health and education of its consumers. As a company dedicated to providing foods of superior value to our consumers, we understand the importance of labeling our brands in a way that accurately reflects each product's attributes and nutrition profile. We work diligently in this regard to ensure that our consumers have all of the information they need to make informed decisions when it comes to purchasing those products that best meet their personal nutrition needs.

This legacy began with our founder, Will Keith Kellogg, who was strongly committed to communicating the important role that good nutrition played in maintaining a healthy lifestyle. He not only sought to bring consumers great-tasting and wholesome cereals, but understood the importance of using our packages to communicate nutrition and ingredient information. In the early 1940's, Kellogg innovation pioneered the concept of fortification by adding nutrients to ready-to-eat cereals. Since then, Kellogg has sponsored many nutrition information programs for consumers and children in schools to stress the importance of eating a healthy, well-balanced breakfast. Beyond that, Kellogg has participated in a number of scientific studies to document the value of ingredients like whole-grains, fiber and antioxidants in creating foods that promote a healthy lifestyle. Our commitment remains to provide consumers with an array of great-tasting and nutritious products for a healthier life.

The food label is a powerful vehicle for conveying important health messages to consumers. Flexible policies that encourage the dissemination of truthful, non-misleading information about diet and health will produce important public health benefits. Accordingly, Kellogg supports

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FDA's efforts to memorialize its approach to qualified health claims and dietary guidance. We offer several comments regarding the qualified health claim approval process, the appropriate wording of health claims, and the benefit of dietary guidance statements.

## **Health Claims**

### **The Qualified Health Claim Approval Process**

Of the three alternative approaches to qualified health claims outlined in the ANPR, Kellogg endorses the first suggested approach—the codification of FDA's interim guidance and evidence-based ranking system into a regulation (Option 1). This flexible approach enables FDA to move expeditiously in allowing appropriately qualified health claims. The approach strikes the appropriate balance between FDA's consumer protection and public health responsibilities.

As currently established, the notice-and-comment period can be quite long and unnecessarily slow the transmission of important health information to consumers. In addition to the burden on FDA, these lengthy notice-and-comment periods stifle the food industry's ability to develop and use qualified health claims. After weighing the benefits of the use of a qualified health claim against the opportunity cost and time necessary for notice-and-comment rulemaking, many food companies may avoid the use of health claims and, therefore, deny consumers the benefit of useful and accurate diet and health information on the food label. In short, these time and opportunity cost concerns have a chilling effect on the provision of useful health information to consumers.

The removal of the time-consuming notice-and-comment period alleviates legal concerns regarding commercial speech while protecting the public and providing interested parties the opportunity to comment on qualified claims. According to Option 1, all qualified claims will remain subject to pre-market approval. This prior approval is a necessary step for several reasons. It helps to protect the public from misleading health claims; it prevents FDA from needing to shift gears to time- and resource-intensive enforcement efforts; and, most importantly, it honors the spirit of the Nutrition Labeling and Education Act, which presupposes a pre-market clearance system for unqualified health claims. FDA should continue to approve unqualified health claims supported by significant scientific agreement. Kellogg urges FDA to continue its practice of allowing such health claims pursuant to publication of an interim final rule.

### **Appropriate Wording of Health Claims**

Kellogg supports the development of four categories of approved health claims as set forth in FDA's July 2003 "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" ("Interim Guidance"). Kellogg cautions, however, that the "appropriate qualifying language" envisioned for each category may be misleading or confusing to consumers. Dictating specific qualifying language would also run afoul of the First Amendment.

Pursuant to the Interim Guidance, those claims accompanied by evidence of significant scientific agreement are deemed Level "A" claims and need not include qualifying language. Claims in the remaining three levels (designated "B," "C," and "D") must include relevant and appropriate qualifying language with examples given below:

B ... "although there is scientific evidence supporting the claim, evidence is not conclusive."

C "Some scientific evidence suggests...however, FDA has determined that this evidence is limited and not conclusive."

D "Very limited and preliminary scientific research suggests...FDA concludes that there is little scientific evidence supporting this claim."

Kellogg believes that the appropriate qualifying language ought to reflect the relevant and significant distinction between the strong A and B claims, on one hand, and the weak C and D claims on the other. The qualifying language should be weighted given the strength of the scientific evidence and not forced into rigid categories. Category "letters" should not be associated with claims. As proposed, the qualifying language does not adequately make this distinction.

Use of "FDA" in any claim might advantage or disadvantage a claim based on consumer bias. Use of "FDA Approved" must be consumer tested. Because it is clear, concise, and conjures the authority of the agency, the "FDA Approved" phrase may well promote consumer confidence. "FDA Approved" is appropriate for Level A and Level B health claims because of the weight of scientific evidence supporting these claims. FDA should also look at the results of its planned consumer research to identify what types of statements best convey the limitations of relatively weak claims that are supported by little by way of scientific evidence.

Finally, unqualified, or Level A claims, should stand out among the range of health claims. Current health claim regulations require unqualified health claims to state that the relevant substance "may" reduce the risk of a specified disease. While the use of the word "may" is meant to convey to consumers the absence of a guarantee that any one dietary practice will, in fact, reduce the risk for disease, it also casts doubt on the science underlying the claim. To avoid this unintended consequence, FDA should revise the regulations by removing the requirement that "may" be included in Level A health claims.

### **Dietary Guidance**

Kellogg concurs with FDA's characterization of dietary guidance statements as "an important component of the Consumer Health Information for Better Nutrition Initiative" and supports the effort to encourage widespread use of such statements. Statements of dietary guidance, as envisioned by FDA, provide useful information on the overall role of diet and health. The nature of statements of dietary guidance is such that FDA pre-approval is not necessary. Hence, based on sound nutrition science, use of dietary guidance provides a flexible, valuable means for food companies to impart useful information to consumers.

One clear way to convey dietary guidance to consumers is through the use of "substitution" or "replacement" guidance. The ANPR provides the example of the recommendation to substitute mono- and poly-unsaturated fats for saturated fats to promote heart health. This type of statement should be encouraged because it is easy for consumers to understand and gives them practical guidance on how to make specific changes in their own diets to improve their health.

Generally, it is useful for FDA to more completely articulate the parameters of allowable dietary guidance. Through use of examples and/or clearly articulating the parameters of such claims, FDA will foster greater regulatory certainty. In turn, food companies will be more likely to utilize dietary guidance statements on food labels. In this regard, Kellogg supports the agency's August 27, 2003 Question and Answer document that discusses the difference between dietary guidance and a health claim.

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FDA has made significant strides in advancing its regulatory framework in a fashion that promotes consumer access to diet and health information via the food label. The issuance of interim guidance by FDA represented an important and necessary recognition that the First Amendment must inform regulation of food label claims. This ANPR raises these issues in a thoughtful manner. Kellogg urges FDA to move expeditiously in adopting regulations that formalize allowance of qualified health claims and broader use of dietary guidance.

Sincerely,



Celeste Clark  
Senior Vice President, Corporate Affairs  
Kellogg Company