



July 6, 2004

**Via Electronic Mail**

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

**Re: Proposed Rule; Reopening of the Comment Period for Food Labeling:  
Nutrient Content Claims, General Principles; Health Claims, General  
Requirements and Other Specific Requirements for Individual Health  
Claims; Docket Nos. 1994P-0390 and 1995P-0241**

Dear Sir or Madam:

We respectfully submit these comments in response to the Food and Drug Administration's reopening of the comment period for the Proposed Rule on "Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of the Comment Period," published in the Federal Register on May 4, 2004 (69 Fed. Reg. 24541).

With projected annual sales of more than \$9 billion, Kellogg is the world's leading producer of cereal and a leading producer of convenience foods, including cookies, crackers, toaster pastries, cereal bars, frozen waffles, meat alternatives, pie crusts and cones. The company's brands include Kellogg's®, Keebler®, Pop-Tarts®, Eggo®, Cheez-It®, Nutri-Grain®, Rice Krispies®, Special K®, Murray®, Austin®, Morningstar Farms®, Famous Amos®, Carr's®, Plantation® and Kashi®. For many of our products, the American Heart Association® certifies that the products meet food criteria for saturated fat and cholesterol, and are recommended for a heart-healthy diet.<sup>1</sup> Our comments below are part of our continuing commitment to promote healthy lifestyles and the importance of good nutrition in helping to maintain health and well-being.

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<sup>1</sup> See [http://www.kelloggs.com/nutrition/hearthealth/hearthealth\\_pg3.shtml](http://www.kelloggs.com/nutrition/hearthealth/hearthealth_pg3.shtml).

## **I. Disclosure Versus Disqualifying Nutrient Levels for Health Claims**

Kellogg supports converting “disqualification levels” of nutrients to “disclosure levels” across the board, rather than in the case-by-case approach currently used by FDA. Kellogg believes that it is inappropriate to stigmatize individual foods as “bad.” There are no bad foods, only bad diets. FDA itself has previously stated that, as to nutrients such as “total fat, saturated fat, cholesterol, and sodium, there are no generally recognized levels at which these nutrients in an individual food pose an increased risk of disease.” 56 Fed. Reg. at 60543 (November 27, 1991) (emphasis added). Kellogg is not aware of any new scientific data that would render this conclusion any less true now than it was in 1991. Even the nutrients listed above have a proper role in the diet at appropriate levels. Disqualifying levels of fat, for example, create artificial barriers that make it unnecessarily difficult for manufacturers to introduce beneficial fats into food products and communicate their benefits to the consumer.

As discussed in *Pearson v. Shalala*,<sup>2</sup> the commercial speech doctrine embodies a preference for disclosure rather than outright suppression. This concept appears directly applicable where there is a choice between disqualification of a claim based on nutrient content or a disclosure requirement as to the nutrient.

Although Kellogg generally supports replacement of disqualifying levels with disclosure levels, when the disqualifying nutrient is not known to be related to the health claim at issue, we believe that neither disqualification nor mandatory “disclosure” with special labeling is appropriate. Consumers who take notice of health or nutrient content claims and take this information into account in purchasing decisions are likely to also read the Nutrition Facts. Nutrients present at disqualifying levels are already required to be listed in the Nutrition Facts. Kellogg believes that the Nutrition Facts panel discloses to consumers the appropriate information for them to be able to manage their diets with respect to these nutrients. Furthermore, it is truthful and not misleading to, for example, make a claim regarding calcium and osteoporosis on the label of a food that is high in calcium, regardless of the content of total fat, saturated fat, cholesterol, and sodium. A young female desiring to bolster her calcium intake to avoid osteoporosis later in life may not need to be concerned that the calcium rich food contains somewhat more than 20% of the Daily Value (equal to the disqualifying level) for one of these nutrients, eg cholesterol, when she maintains a balanced diet.

## **II. Use of “May” in Health Claims**

Kellogg supports removing the requirement to use the word “may” or “might” to describe the ability of a substance to reduce the risk of a disease or health related condition for claims based on significant scientific agreement. We believe that these words imply that there is not significant scientific agreement on the effect of a substance on a disease or health related condition, when in fact, there is. Although diseases mentioned in health claims are indeed “multifactorial” (which is what led FDA to require the “may” or “might” verbiage), this is already reflected by the use of the term “risk.” A

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<sup>2</sup> 164 F.3d 650 (D.C. Cir. 1999).

consumer reading the claim “reduces the risk of heart disease” on a product containing requisite levels of, e.g., whole grain fiber cannot reasonably conclude that consuming the product will eliminate any chance of heart disease. On the other hand, a consumer reading the claim “may reduce the risk of heart disease” is left uncertain as to whether there is any real risk reduction from consuming the specified amount of whole grain fiber, and thus may not give the claim any credence. Thus, the combination of “may” and “risk” is redundant for claims that are based on significant scientific agreement, and should be reserved for “qualified” health claims where there is less than significant scientific agreement.

### **III. Synonyms for Nutrient Content Claims**

While Kellogg does not currently possess any consumer research with respect to synonyms for nutrient content claims, Kellogg does believe that it is in the best interest of the consumer to keep a fairly limited list of terms. Thus, Kellogg does not support the proposed revisions to § 101.13(r) in the 1995 proposal. 60 Fed. Reg. 66206 (December 21, 1995). FDA has already established a fair number of synonyms for each class of nutrient content claims, to which consumers have grown accustomed over the years. Some of the nutrient content claims that industry has suggested in previous comments may be more appealing from a marketing perspective, e.g., “loaded with” instead of “excellent source” or “smidgen” instead of “low.” Our sense (albeit in the absence of consumer perception data) is that consumers would interpret these claims to be different from, and more extreme than, the approved claims. This effect on perception would not be entirely mitigated by the proposal to “anchor” to a defined claim. Under the anchor scenario, Kellogg anticipates that aggressive marketing efforts would lead to claims that test the limits, resulting in consumer confusion and a drain on Agency resources if it attempts to police the marketplace. Kellogg does not oppose updating the lists of defined nutrient content claim synonyms based on data demonstrating that consumers understand the claims. If such data are lacking in the current rulemaking, Kellogg submits that it would be appropriate to (1) decline to expand the list and (2) to maintain the current petition process at 21 C.F.R. § 101.69(n) for clearing new synonyms.

### **IV. Abbreviated Health Claims**

Kellogg supports the proposal to allow abbreviated health claims with a reference to the complete claim language elsewhere on the label, not necessarily the principal display panel (PDP). However, the 1995 proposal would have only authorized this approach where specifically allowed by a health claim regulation in Subpart E, which FDA limited to the health claim for calcium and osteoporosis at § 101.72. Kellogg supports a more flexible treatment of abbreviated claims, whereby a manufacturer could use an abbreviated version of any authorized health claim, provided such claim is truthful and not misleading. One approach would be to require manufacturers to possess consumer perception data demonstrating that consumers understand the message. Kellogg also believes that FDA should allow “split” claims, in which part of the claim appears, e.g., on the PDP, with a link such as an asterisk to the remainder of the claim, which may appear elsewhere on the label. For example, the model claim authorized under § 101.75(e)(5) could be split as follows:

**PDP:**

Diets low in saturated fat, cholesterol, and total fat (may)<sup>3</sup> reduce the risk of heart disease.\*

\* (See side panel for more information.)

**Information Panel (IP):**

\* Heart disease is dependent upon many factors, including diet, a family history of the disease, elevated blood LDL-cholesterol levels, and physical inactivity.

There are numerous examples of such split claims currently in the marketplace, apparently with little or no enforcement action by FDA. If FDA chooses not to enforce the current rule requiring the entire claim to appear in one place without intervening material, Kellogg respectfully submits that the rule should be changed to provide a level playing field for manufacturers that follow the regulations. As discussed above, Kellogg believes that those consumers who take interest in health claims are also likely to review the Nutrition Facts and ingredient list, and would also read the complete claim on the IP. If FDA is concerned that the full claim language might somehow become "lost" in the printed material on the label, it could require that such claim language be required to be set off in a distinctive and standardized format in a specified location such as the IP.

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Kellogg appreciates the opportunity to provide comments on the proposed rulemaking discussed above. Please let us know if you would like any further information.

Respectfully submitted,



C. A. Clark, PhD  
Senior Vice President, Corporate Affairs

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<sup>3</sup> As discussed above, Kellogg supports eliminating the requirement to use "may" or "might" in conjunction with reduced "risk" claims for which there is significant scientific agreement.