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Food and Drug Administration
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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

Dear Sir or Madam:

For over 100 years, Americans have trusted the well-known brands Kraft Foods Global, Inc. (Kraft) sells. Kraft is a $30 billion company, the largest food manufacturer in North America, and the second largest worldwide. Today, Kraft brands are found in more than 99% of all U.S. households and are sold in 150 countries around the world. Kraft is at the forefront of the food industry's effort to provide consumers with a broad array of choices from which to select foods consistent with a healthy diet, which of course requires the company to communicate the benefits of various foods to consumers. Accordingly, Kraft has a strong and substantial interest in the regulation of nutrient content and health claims.

Kraft submitted comments on this rulemaking in 1996 and again in March 1997, which are already part of the record. When those comments were filed, we expressed our view that some of the requirements governing the use of nutrient content and health claims on labels are so stringent they hamper the communication of beneficial health and nutrition information to consumers. Kraft continues to believe that is the case. Accordingly, we applaud the agency's renewed interest in modifying the rules to provide greater flexibility and, thereby, to give companies like Kraft the opportunity to share important information about diet and health with consumers.

The changes proposed by FDA in 1995 represent a thoughtful first step. Nonetheless, our experience convinces us that far more can be done to ensure that FDA rules encourage the flow of beneficial information to consumers. Relatively recent developments in First Amendment jurisprudence related to the communication of diet and health relationships on food labels influence our view in this regard. The value the First Amendment places on the free flow of information obligates FDA to construct its limitations on claims as narrowly as possible, and to choose disclosure over outright bans, except in those limited circumstances in which disclosure cannot cure a

misleading impression. This fundamental principle has direct application to several of the issues under consideration in this rulemaking, as explained further below.

Our recommendations on how FDA should amend the regulations, both to provide much needed flexibility and to comport with the demands of the First Amendment, follow. We hope the agency will accept these recommendations in the same cooperative spirit in which they are offered and that FDA will give our suggestions serious consideration as the agency prepares a final rule.

1. Minimum Nutrient Contribution Requirement

In the 1993 regulations implementing the health claims provisions of the Nutrition Labeling and Education Act (NLEA), FDA included a requirement that a food bearing a health claim must contain at least 10 percent of the Daily Value (DV) for vitamin A, vitamin C, calcium, iron, protein or fiber, prior to any nutrient addition. This requirement is often referred to as the "jelly bean rule". At the time, FDA reasoned that the rule was needed to prevent health claims from being used on foods with little or no nutritional value.

In the 1995 proposed rule, FDA recognized that the minimum nutrient contribution requirement may have the unintended effect of prohibiting health claims on foods that contribute to a healthful diet. To address that undesirable consequence, the agency proposed to exempt from the requirement fruits and vegetables, enriched grain products, and most breads.

Over the intervening years, on several occasions FDA has expanded the list of exemptions to the minimum nutrient contribution requirement. Specifically, in approving several health claims FDA determined that the jelly bean rule, if imposed, would suppress valuable health claim information. *See, e.g.,* 21 C.F.R. § 101.80 (noncariogenic carbohydrate sweeteners/dental caries); 21 C.F.R. § 101.83 (plant sterol/stanol esters and CHD); qualified health claim for monounsaturated fatty acids from olive oil (November 1, 2004).

Kraft respectfully suggests that the remedy to the problem created by the 10 percent DV minimum nutrient contribution requirement is not to create additional exceptions to the rule on a case-by-case basis but to eliminate the rule entirely. In our view, there has never been a defensible nexus between the 10 percent DV requirement and the authorization of health claims. As we observed in 1996, health claims communicate information about the effects of the nutrients in foods when consumed as part of a diet over time. Thus, the 10 percent DV requirement is not a reasonable proxy for determining whether and how a particular food may fit into an overall healthful diet.

Kraft also questions whether continued use of the 10 percent DV requirement is fully consistent with the demands of the First Amendment. Recent court decisions emphasize the agency's obligation to establish limitations on claims that are

no more extensive than necessary to prevent deception. *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002). Even with the limited, category specific exceptions to the 10 percent DV requirement the agency has already proposed (e.g., fruits and vegetables, a few grain products), the current rule would still ban outright the use of health claims on a numerous foods, including for example foods that contribute meaningful amounts of whole grains to the diet.

That broad disqualification seems particularly troublesome in light of the ever evolving nature of nutrition science and the complex relationship between diet and health. As research enhances our knowledge in this area, the components of what is considered an optimal diet, and the foods that may play a role in that diet, change. The rigid, 10 percent DV minimum nutrient contribution requirement is at odds with this basic axiom. The food specific nutrition information already required on labels, together with the text of an approved health claim, provide the information consumers need to determine whether a particular food bearing a health claim is an appropriate dietary choice.

If, despite these considerations, FDA is unwilling to eliminate the 10 percent DV minimum nutrient contribution requirement altogether, Kraft still urges the agency to consider fundamental changes to better tailor the requirement to the goal of providing consumers with useful information. One approach would be to permit satisfaction of the 10 percent DV requirement through fortification. FDA has already adopted this approach in defining the term "healthy." 21 C.F.R. Section 101.65(d). There is no evident basis for treating health claims any differently.

Kraft also urges the agency to update the nutrients evaluated in determining whether a food makes more than a minimal contribution to the diet. Specifically, based on the 2004 Dietary Guidelines Advisory Committee Report, Kraft suggests that the list of nutrients should include vitamins A, C, E and D (provided fortification is permitted), as well as calcium, iron, magnesium, potassium, protein and fiber.[1/]

[1/] In our 1996 comments on this rulemaking, Kraft offered three comments on the agency's narrow proposal to amend the 10 percent minimum nutrient requirement by creating limited, additional exemptions. For purposes of completeness, we reiterate those three comments here. Again, however, we stress our view that the proper response to concerns about the 10 percent minimum nutrient requirement is to abolish the requirement altogether, not to create additional exemptions.

- The agency proposes to exempt bread which conforms to a standard of identity but for its grain composition (e.g., 12-grain bread). Such bread is essentially a nonstandarized food that follows the enrichment scheme for standardized bread. Other non-standardized grain-based products that fall in this category include brown rice and bagels. These foods can make a nutritional contribution to the diet and are consistent with dietary guidelines yet are excluded from health claims by the 10 percent requirement. These

2. Disqualifying Nutrient Levels

In 1996, Kraft joined NFPA and others in urging the agency to transform the disqualifying levels for health claims into disclosure levels, recommending that a health claim be prohibited only if the nutrient that exceeds the disqualifying level is related to the specific health claim being made. When a disqualifying nutrient is not related to the specific health claim involved, Kraft suggested that the nutrient could be disclosed through referral statements, similar to those employed in connection with nutrient content claims.

The previously cited court decisions only underscore the need for significant change in this area of the agency's regulation of health claims. The First Amendment demands disclosure over outright disqualification, except in those narrow circumstances in which FDA can establish that disclosure cannot cure the misleading impression conveyed. In the case of health claims, a statement directing a consumer to see the nutrition facts for information about specific, named nutrients in a product bearing a claim will provide the necessary disclosure. Kraft notes, moreover, that consumers are accustomed to seeing this type of referral statement in connection with foods that bear nutrient content claims but which contain levels of nutrients that exceed the disclosure levels in 21 C.F.R. Section 101.13(h).

Accordingly, Kraft again urges the agency to transform the disqualifying levels into disclosure levels. In those circumstances in which the nutrient that exceeds the current disqualifying level is unrelated to the disease at issue, disclosure through a referral statement would put consumers on notice that the food may not necessarily be healthful in all respects. In those circumstances in which the nutrient that exceeds the current disqualifying level relates closely to the disease at issue, *Pearson* and related cases now require a more complex inquiry than that proposed by NFPA, Kraft and others in 1995-96.[2/] Only if FDA can demonstrate through testing or otherwise that

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foods should also be included in any expanded exemption from the 10 percent requirement.

- Breakfast cereals are traditionally fortified foods, and there is no evidence that nutrients are added to these foods for the sole purpose of qualifying for health claims. Kraft concludes, therefore, that breakfast cereals meet the exception to the restriction on added nutrients in the existing regulation. See 60 Fed. Reg. 66123, 58 Fed. Reg. 44037, 58 Fed. Reg. 2522.

- Kraft understands that the restriction on nutrient addition does not apply to modified food products that are fortified to meet the nutrition equivalency requirement at 21 C.F.R. Section 101.3(e).

[2/] In our estimation, this situation should rarely, if ever, arise. If a nutrient is closely related to the development of the disease highlighted in the claim, the level of that nutrient will almost always be a requirement for qualification for the claim (e.g., low saturated fat).

disclosure is inadequate to convey the limitations of the labeled food in constructing a healthful diet and achieving the benefits of the health claim would a ban on the claim be appropriate. In all other instances, to satisfy the First Amendment, FDA must permit disclosure rather than ban the claim.

Although moving to a disclosure-based system for addressing the disqualifying nutrients (i.e., nutrients that are present at levels that increase the risk of diet-related disease) would significantly advance the agency's interest in encouraging the flow of beneficial health information to consumers, it would leave unaddressed another arguably more significant barrier to the use of both nutrient content and health claims on foods—the 50-gram rule. Whether a food with a small serving complies with some of the criteria for approved health claims, such as the requirement that the food meet the nutrient content claim criteria for "low fat," is assessed on the basis of 50 g of the food, not simply on a serving or reference amount of the food. In effect, therefore, the criteria for many health claims are applied to an amount of food that may be almost twice the amount commonly eaten by consumers at a sitting.

The result, in our experience, has been a significant restraint on the ability of companies to market "low fat" foods and to use health claims on small serving size foods, including foods like cheese that are generally recommended for consumption as part of a healthy diet. While we recognize that FDA has rejected arguments critical of the 50-gram rule in the past, to the best of our knowledge the issue has not been considered for a number of years. Accordingly, we ask the agency to reconsider application of the 50-gram rule in light of the importance of enhancing the flow of beneficial health information to consumers. An appropriate first step, in our view, would be for the agency to eliminate the 50-gram rule from the "low fat" criteria in the various health claims the agency has approved to date, consistent with current recommendations of the Institute of Medicine of the National Academy of Sciences (Food and Nutrition Board, 2002) and the Nutrition Subcommittee of the FDA Food Advisory Committee.

3. Use of the Word "May" in Unqualified Health Claims

As FDA has observed on many occasions, chronic diseases are multi-factorial in nature, which makes it difficult, if not impossible, to link a specific reduction in disease risk to the ingestion of a particular food. FDA prudently requires health claims to contain language that conveys this important limitation to consumers. The language used should help consumers understand that a health claim is not intended to be a guarantee that consumption of the food will necessarily reduce their individual risk of developing a disease, or do so by any specific amount.

In 1995, FDA proposed to make optional the statement in many approved significant scientific agreement (SSA) health claims that development of the disease depends upon many factors. FDA cited the common understanding among consumers that the onset of chronic disease is due to many factors, as well as the existing

requirement that health claims use “may” or “might” to describe the ability of the highlighted substance to reduce the risk of the disease that is the subject of the claim. Kraft supported that proposed change in 1996 and continues to do so today.

FDA now questions whether the use of “may” or “might” to describe the ability of a highlighted substance to reduce the risk of disease should be eliminated or replaced by a separate, additional statement that conveys the multi-factorial nature of chronic disease. The agency is considering whether this change may be necessary to dispel the potential impression, created by the words “may” or “might,” that the science supporting the claim is uncertain.

Kraft is aware of no definitive evidence demonstrating that consumers interpret the words “may” or “might” in significant scientific agreement health claims as suggesting that the science underlying the claim is uncertain. In the absence of such evidence, the rules should permit companies to communicate the multi-factorial nature of chronic diseases using whatever language fairly conveys this message to consumers. For many, this language likely will continue to be use of terms like “may reduce” or “might reduce.”

4. <u>Synonyms in Nutrient Content Claims</u>

In 1995, FDA proposed to allow the use of unlisted synonyms for nutrient content claims on labels, provided 1) the unlisted synonym is anchored to a defined term; 2) the unlisted synonym is not misleading in the context of the entire label; 3) the unlisted synonym is reasonably understood by consumers to be a synonym of the defined term; and 4) the defined term appears prominently and conspicuously on the label. Although we have previously expressed support for the agency’s overall effort in this regard, Kraft continues to believe the agency’s proposed approach is unnecessarily complex.

The “anchoring” requirement is particularly puzzling. As we observed in 1996, the impetus behind “anchoring” seems to be the agency’s concern that consumers may not understand a particular unlisted term to be synonymous with a particular authorized claim. Yet, if consumers do not understand a particular unlisted term to be a synonym for a defined term, then the term is not by definition a synonym and should not be used at all. In short, when a term is a true synonym for a defined claim, anchoring is unnecessary and redundant.

The anchoring requirement also seems highly suspect as a matter of law. Again, the treatment of First Amendment questions by the courts since the implementation of NLEA has helped delineate the limits of FDA authority with respect to its regulations of claims. The agency’s 1995 proposal reflects an assumption that the law permits FDA to ban all synonyms for defined nutrient content claims unless food companies anchor the claim to a defined term and offers evidence that consumers understand the unlisted synonym to be part of a single nutrient content claim. Kraft

respectfully suggests that the law places the burden on FDA, not food companies, to justify a position that bans the use of synonyms for defined terms. In the absence of data demonstrating that consumers misunderstand and are misled by the use of unlisted synonyms, FDA simply has not carried its burden. Accordingly, FDA's rules should permit unlisted synonyms and, as Kraft argued in 1996, permit them without the use of redundant and unnecessary "anchoring."

5. Abbreviated Health Claims

In 1995, FDA recognized the need for additional flexibility in the manner in which health claims are presented but again proposed very limited steps in that direction. Rather than allow highly abbreviated, split claims in all instances in which such a format is capable of conveying a non-misleading, scientifically valid representation of the substance/disease relationship, the agency proposed only to permit abbreviated claims when specifically authorized in the regulation authorizing the claim.

Kraft continues to believe this limited approach to the abbreviation of health claims wastes a valuable opportunity. The lengthy and cumbersome language mandated in the individual health claim regulations – information that must appear together, in one place – limits the ability of food companies to communicate health-related information to consumers in the most effective manner possible. Rules that permit abbreviation of these claim "paragraphs," with cross references to another label panel where all mandatory elements of the health claim appear, would give companies the flexibility they need to make health claims more readily understandable to consumers. Better-understood claims, of course, would directly further the agency's goal of providing more beneficial information to consumers, empowering them to make sound dietary choices.

Available research on consumers' understanding of health claims directly supports this change. FDA's own experimental study, as well as two studies by Quaker Oats, show that abbreviating a SSA health claim does not lead consumers to draw erroneous conclusions about the strength of the underlying science or about the need to adopt or continue certain lifestyle habits that contribute to attainment of the health benefit. Kraft discussed the results of these studies at greater length in its March 1997 comments on this rulemaking.

For these reasons, we urge FDA to permit the use of highly abbreviated, "split" claims on the principal display panel of a food, with a cross-reference to the location elsewhere on the label where the full health claim information appears. The company making the claim would have the responsibility of ensuring that the split presentation it chooses is truthful, accurate and does not mislead consumers. Of course, FDA would retain the authority to challenge any particular abbreviated claim presentation as false or misleading under Section 403(a) of the Act.

This flexible approach to the presentation of health claim information would give companies the freedom they need to improve the communication of health-related information to consumers. It would also better reflect the agency's First Amendment obligation to tailor its rules as narrowly as possible to prevent deceptive claims. In short, if a highly abbreviated claim can be made in a truthful, non-misleading fashion, the agency's rules should allow the claim.

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Once again, we applaud the agency's renewed interest in modifying its nutrient content and health claim regulations to promote needed flexibility and, thereby, allow the food companies to better convey valuable nutrition and health information to consumers. We appreciate the opportunity to comment on these important issues.

Respectfully submitted,

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