



April 18, 2006

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

**RE: Docket No. 2006D-0066  
Draft Guidance for Industry and FDA Staff:  
Whole Grain Label Statements**

Dear Sir/Madam:

Kraft Foods Global, Inc. (Kraft) is pleased to submit these comments on FDA's Draft Guidance for Industry and FDA Staff on Whole Grain Label Statements (the draft guidance). For over 100 years, Americans have trusted the well-known brands Kraft sells. Kraft is a \$34 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 in over 155 countries worldwide.

As the distributor of over 18 billion packages of food each year, Kraft's interest in the regulation of all types of label statements is substantial. Our interest in whole grain label statements is particularly significant given the breadth of our grain-based product portfolio, including POST cereals, NABISCO cookies and crackers, and KRAFT macaroni and cheese dinners.

## INTRODUCTION

Kraft appreciates FDA's efforts in preparing the draft guidance. A common understanding about basic issues like what constitutes whole grain is important for FDA and industry as consumer interest in identifying foods that provide significant amounts of whole grain grows. Kraft is committed to helping consumers increase their consumption of whole grains, as recommended by the *2005 Dietary Guidelines for Americans* and other prominent nutrition authorities. In addition to producing several 100% whole grain foods (e.g., SHREDDED WHEAT, MINUTE instant brown rice), Kraft has reformulated many existing products and developed others to provide consumers with additional opportunities to increase

their consumption of whole grains. For example, Kraft has introduced a line of Nabisco-branded snacks made with grain ingredients that are 100% whole grain, including Baked with 100% Whole Grain WHEAT THINS baked snack crackers and Baked with 100% Whole Grain CHIPS AHOY! chocolate chip cookies. Kraft has also developed educational materials for registered dietitians to help them teach consumers how to incorporate more whole grains into a balanced eating plan.

### **A. Definition of Whole Grain**

Kraft agrees with the definition of whole grains put forward in the draft guidance. We also support the agency's tentative conclusion that soybeans, chickpeas, legumes, oilseeds, and roots are not cereal grains and, therefore, should not be considered whole grains.

In general, we support the manner in which the agency proposes to apply the definition of whole grain. For example, we support the agency's tentative conclusion that corn flour and corn meal must include the pericarp to qualify as whole grain. It is our understanding, however, that nixtimalization -- a process commonly used in the production of corn-based products like flour and meal -- typically removes all or a substantial portion of the pericarp.<sup>1</sup> Given the widespread use of nixtimalization, we believe the agency could prevent misunderstanding by stating clearly in the final guidance what portion, if any, of the pericarp may be lost during nixtimalization without disqualifying the resulting flour/meal as whole grain.

### **B. Whole Grain Label Statements**

Kraft welcomes the agency's attempt to offer some preliminary guidance regarding whole grain label statements. Despite the recommendations in the 2005 *Dietary Guidelines for Americans*, consumers continue to fall short when it comes to whole grain consumption. One of the most effective means of bringing foods that contain nutritionally significant quantities of whole grain to consumers' attention is through the food label. Toward that end, we believe FDA's guidance should encourage manufacturers to make label statements about whole grain content, provided the overall impression created by the label is neither false nor misleading.

The draft guidance states that factual statements about whole grain content are permissible, but goes on to impose two qualifications -- "the statements are not false or misleading under section 403(a) of the Act and do not imply a particular level of the ingredient, i.e., 'high' or 'excellent source.'" We agree fully

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<sup>1</sup> See *Corn: Chemistry & Technology* pp. 512-13 and Table 7, p. 101 (noting that 50% of the fiber in a corn kernel resides in the pericarp) (2<sup>nd</sup> ed. White & Johnson, editors).

with the first qualification. We consider any label statement about whole grain content (including terms like “excellent source” of whole grain) to be inappropriate if the label on which it appears leaves consumers with a false or misleading impression about the product’s whole grain content. We respectfully disagree with the second qualification, however, to the extent it is meant to suggest that terms like “good” or “excellent source” of whole grain are somehow *per se* inappropriate.

1. Kraft Uses the Terms “Good” and “Excellent Source” of Whole Grain in a Truthful, Nonmisleading Manner

Because the terms “good” and “excellent source” are familiar to consumers and well known as signifying a nutritionally significant amount of the substance highlighted, they are powerful tools in encouraging consumers to incorporate more whole grains into their diets. Using the *2005 Dietary Guidelines* and other consensus nutrition recommendations as a reference, terms like “good” and “excellent source” of whole grain can be used on food labels in a truthful, nonmisleading manner. We are confident that our use of these terms satisfies that standard.

a. Direct Reliance on the 2005 Dietary Guidelines

Both the *Dietary Guidelines* and MyPyramid recommend that consumers increase their whole grain consumption and “make half [their] grains whole.” Because the Guidelines recommend about six servings of grains per day for most adults, this means eating at least three servings (also referred to as “ounce-equivalents”) of whole grain foods per day. Drawing on the U.S. Department of Agriculture’s (USDA) determination that a serving of grain contains 16 grams of flour, we translate the *Dietary Guidelines*’ recommendations into quantitative terms. Thus, a serving (or “ounce-equivalent”) of whole grain food contains at least 16 g of whole grain, and the daily minimum recommended amount of whole grain is 48 g.

Kraft uses “excellent source of whole grain” to describe products that provide at least 16 g of whole grains per serving and “good source of whole grain” to describe products containing at least 8 g. The levels chosen are the quantitative equivalent of a full and half serving of whole grain food, respectively. To us, there is no doubt that they are nutritionally significant and appropriate for use in connection with the “good” and “excellent source” terminology.<sup>2 & 3</sup>

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<sup>2</sup> We understand that opinions differ as to whether an “ounce-equivalent” of whole grain is properly quantified as 16 g (using the flour content of bread as a reference) or 28 g (literally, one ounce of whole grain). For the reasons discussed above, we believe the correct value is 16 g. Nonetheless, should the agency determine that an “ounce-equivalent” of whole grain is properly regarded as 28 g of whole grain, 3 ounce-equivalents of whole grains per day would yield a minimum daily recommended consumption of 84 g per day. Following the agency’s framework for defining “good” and “excellent source” for purposes of establishing nutrient content claims, 10% of 84 is approximately 8 g, and 20% of 84 is approximately 16 g. Thus, regardless of how “ounce-equivalent”

b. Impression Created by the Entire Label

Of course, Kraft's use of terms like "good" and "excellent source" of whole grain does not occur in a vacuum. Our labels typically include additional information about whole grains. This information enhances the clarity of our whole grain message and bolsters our confidence that our labels convey a truthful, nonmisleading impression with respect to whole grain content.

For example, Kraft labels generally disclose the quantitative amount of whole grain per serving in conjunction with good source, excellent source, and related claims. Some labels repeat the recommendations regarding whole grain consumption in the *Dietary Guidelines* and accompany them with the MyPyramid graphic. Our label for TRISCUIT whole grain wheat crackers (copy attached) is an excellent example of this approach.

2. "Excellent Source" and Similar Terms Should Not Be Treated as Per Se Inappropriate

Although unstated, the agency's objection to terms like "good" and "excellent source" appears to be founded on the belief that such claims are inconsistent with Section 403(r) of the Act.<sup>4</sup> To the extent that is the case, we again respectfully disagree. In our view, whole grains are a substance, not a nutrient, and, thus, claims about them fall outside the scope of Section 403(r).<sup>5</sup> The agency's recent acknowledgement that "the health benefits of whole grains are based on more than just fiber content" reinforces our view.<sup>6</sup> As a substance, claims about whole grains are appropriately regulated under the agency's general authority to prohibit false and misleading labeling.<sup>7</sup>

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is quantified, we are confident the levels we have chosen to support "good" and "excellent source" claims represent a nutritionally significant level of whole grain.

<sup>3</sup> FDA suggested many years ago that references to whole grain content might convey an implied message about fiber. Since that time, however, knowledge and appreciation of the many benefits of whole grains have grown. The benefits of whole grain are now widely recognized as extending far beyond fiber, and the agency itself has acknowledged this. Our internal standards governing whole grain label statements like "good" and "excellent source" accordingly include no minimum fiber requirements.

<sup>4</sup> 21 U.S.C. § 343(r).

<sup>5</sup> "Substance means a specific food or component of food . . ." 21 C.F.R. 101.14(a)(2). Because whole grains occur both as foods themselves (popcorn, rolled oats, brown rice) and as components/ingredients in other foods (whole wheat flour in whole wheat bread), they are properly regarded as a substance.

<sup>6</sup> See Letter to Judi Adams, Grain Foods Foundation from Shellee Anderson, Food Labeling and Standards Staff, CFSN (January 24, 2006).

<sup>7</sup> 21 U.S.C. § 343(a).

Nonetheless, we recognize that past use of terms like “good” and “excellent source” has been limited to defined nutrient content claims, established by regulation or through a FDAMA notification. We also recognize that opinions differ as to whether whole grains are properly considered a food category, an ingredient, a substance, a nutrient or “something else.” In fact, the agency has stated that careful consideration of this issue is necessary before it can begin to define “good source,” “excellent source,” and similar terms for use in connection with whole grains. Kraft looks forward to participating fully in the dialogue to come on this important issue.

In the interim, classifying “good source,” “excellent source,” and similar terms as categorically inappropriate for use in connection with whole grain-containing foods seems premature, at best. In the absence of guidance from the agency (whether by regulation or less formal “policy”) about how to formulate label statements that highlight for consumers products that contain significant amounts of whole grain, industry leaders like Kraft used their best judgment. They looked to the *2005 Dietary Guidelines* and selected quantitative levels they believed reflected the messages conveyed by familiar terms like “good source,” “excellent source” and “made with.” Now the agency seems to be suggesting that this approach is inappropriate, yet it cites no legal basis for its tentative conclusion and offers no substitute approach.

### 3. Whole Grain Pizza and Bagels

The draft guidance also includes troubling statements about whole grain descriptors for pizza and bagels. In its answer to Question #7, the agency states that the terms “whole grain (or “whole wheat”) pizza” and “whole grain (or “whole wheat”) bagels” should be limited to products in which the flour component is entirely whole grain. Again, the legal basis for the agency’s position is unclear, as there are no standards of identity governing the composition of pizza and bagels that mandate the use of whole grain flour. The agency’s position is also inconsistent with FSIS’s interim policy on whole grains. FSIS permits the use of “whole grain” as a descriptor for “FDA components that are not the subject of a standard of identity, provided that at least 51% of the grain components are whole grain” and the descriptor is not otherwise misleading.<sup>8</sup> We urge the agency to reconsider its position and modify the draft guidance in accordance with governing law and FSIS policy.

## CONCLUSION

A growing number of consumers understand the importance of increasing whole grain intake. Much work remains to increase consumption to

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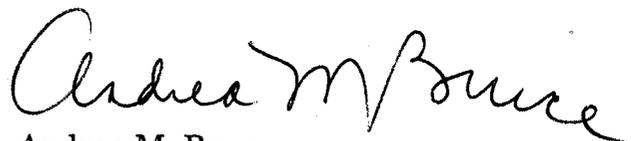
<sup>8</sup> Food Safety and Inspection Service (FSIS) Statement of Interim Policy Guidance: Use of the USDA *MyPyramid* Reference on Meat and Poultry Labeling and Whole Grain Claims.

recommended levels, however, and companies like Kraft are responding with new and reformulated products. In light of these considerations, we believe FDA would best serve the interests of consumers and the companies trying to meet their needs by modifying its discussion of label claims in the draft guidance in one of two ways:

1. Acknowledge that familiar terms like “good” and “excellent source” are powerful tools in identifying products that contain nutritionally significant amounts of whole grain and articulate the specific quantitative levels the agency believes are appropriate to support their use pending completion of rulemaking on this topic; OR
2. Clarify the answer to Question #10 to make clear that enforcement action against manufacturers’ use of terms that imply a particular level of whole grain (e.g., “excellent source”) will occur only when the labels in which they appear, when considered in their entirety, create a false or misleading impression about whole grain content, and thus, violate Section 403(a) of the Act.

Kraft appreciates the opportunity to comment on the draft guidance and looks forward to working cooperatively with the agency on future activities relating to whole grains.

Respectfully submitted,



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Enclosure