

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**RE: Docket No. 2006D-0066; Draft Guidance for Industry  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 Grains Label Statements**

The Grocery Manufacturers Association (GMA) submits these comments regarding the Food and Drug Administration's (FDA) Draft Guidance for Whole Grain Label Statements ("Draft Guidance"). GMA is the Washington, D.C. – based organization representing the world's leading branded food, beverage, and consumer product companies. GMA member companies employ more than 2.5 million workers in all fifty states and account for more than \$680 billion in annual sales.

**INTRODUCTION**

GMA applauds FDA for taking a needed first step in developing draft guidance to industry regarding whole grain label statements. GMA appreciates the agency's attention to this issue and the agency's desire to promote whole grain consumption. We strongly support allowing food manufacturers to communicate the presence of whole grains in their products to consumers. We believe that permitting whole grain label statements is appropriate and will assist consumers wishing to incorporate whole grain products into their diets in accordance with the recommendations of the 2005 *Dietary Guidelines for Americans* ("*Dietary Guidelines*").

However, we disagree with the agency's conclusion that label statements characterizing the amount of whole grains present in food are inappropriate. Such claims are not inherently improper, but rather, should be evaluated in the context of the entire food label to determine if they are misleading. Food manufacturers who wish to add a variety of whole grains to an assortment of their products in meaningful amounts should be able to characterize the amount of whole grains present in ways that makes that

information meaningful to consumers. GMA believes that quantitative statements regarding whole grains can be improved upon in order to assist consumers attempting to follow the *Dietary Guidelines*. Manufacturers should be encouraged to place quantitative statements into the context together with other information conveying the recommended consumption of at least 48 grams of whole grains daily, as well as provide a direct reference or link to MyPyramid. Moreover, statements characterizing the amount of whole grains present, such as “good source” and “excellent source,” should also be allowed for those foods that contribute meaningful amounts of whole grains, either within the broader context of the daily diet or as defined, stand-alone terms. Additionally, certain products should be permitted to use a whole grain descriptor as a characterizing term in the product name (e.g. “whole wheat bagel”).

We also ask the agency to review its conclusion that pearled barley should not be considered a whole grain. This determination is unworkable because, as the agency acknowledges in the Draft Guidance, humans can not reasonably consume barley that has not been dehulled, nor is barley nutritionally bioavailable to humans unless it is has been processed. It is also extremely difficult to dehull barley and thus it is customarily processed. FDA should clarify that as long as barley has been minimally processed such that the starchy endosperm, germ and bran are present, in as close as possible to the same relative proportions as exist in the intact caryopsis, it should be considered a whole grain.

## **BACKGROUND**

With the release of the 2005 *Dietary Guidelines for Americans* (“*Dietary Guidelines*”) and the Food Guidance System (“MyPyramid”), the Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) have encouraged Americans to increase significantly their consumption of whole grains. These guidelines provide quantitative recommendations for whole grain consumption. The recommendations state that Americans, based on a 2,000 calorie diet, should consume (1) at least 3 one ounce-equivalents of whole grains per day (which translates to at least 48 grams per day), and (2) at least one-half of all grain intake should be whole grains (“make half your grains whole”). Indeed, the recommendation that American consumers increase their consumption of whole grains is one of the centerpieces of the *Dietary Guidelines* and MyPyramid.

The *Dietary Guidelines* and MyPyramid make this recommendation regarding whole grain consumption because whole grains can provide a number of important health benefits, starting with the health benefits of fiber. As reiterated in MyPyramid materials, “consuming foods

rich in fiber, such as whole grains, reduces the risk of coronary heart disease.” But whole grains also contribute much more to the diet than simply providing fiber. For example:

- As the MyPyramid materials also stated, “eating at least 3 ounce-equivalents of whole grains may help with weight management.” [1/](#)
- Additionally, “people who eat whole grains as part of a healthy diet have a reduced risk of some chronic diseases.” [2/](#)
- As the advisory committee for the *Dietary Guidelines* stated in its report: “One potential mechanism by which whole grains may decrease risk of [coronary heart disease] is through their antioxidant content.” [3/](#)
- Whole grains are an important source of several B vitamins, such as thiamin, riboflavin, niacin, and folate. [4/](#)
- Whole grains are also a source of the minerals iron, magnesium, and selenium. [5/](#)

More recent research conducted by the Agricultural Research Service division of USDA provides further insight as to how whole grain foods benefit the human body by keeping tryglicerides (a fat, or lipid) “at levels healthful for [the] heart.” [6/](#)

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[1/](#) *Inside the Pyramid, Why Is It Important to Eat Grains, Especially Whole Grains*, available at [www.mypyramid.gov/pyramid/grains\\_why.html](http://www.mypyramid.gov/pyramid/grains_why.html) (last visited Apr. 17, 2006).

[2/](#) *Id.*

[3/](#) *2005 Dietary Guidelines Advisory Committee Report, Part D: Science Base, Section 6: Selected Food Groups 10*, available at <http://www.health.gov/DietaryGuidelines/dga2005/report/> (last visited Apr. 17, 2006).

[4/](#) *Inside the Pyramid, Why Is It Important to Eat Grains, Especially Whole Grains*, available at [www.mypyramid.gov/pyramid/grains\\_why.html](http://www.mypyramid.gov/pyramid/grains_why.html) (last visited Apr. 17, 2006).

[5/](#) *Id.*

[6/](#) Marcia Wood, “Whole Grain Foods’ Fat Fighting Role Scrutinized.” *Agricultural Research Service* 20 (Mar. 2006).

Nonetheless, despite these benefits, about 95 percent of Americans consume less than a single serving of whole grains per day. <sup>7/</sup> That is why finding innovative ways to raise the consciousness of American consumers about whole grains and provide them with useful information for making better dietary choices is so important, and why relying on very limited, historically based labeling solutions is simply not adequate. Given the importance of the recommendations regarding whole grains, “business as usual” is not acceptable from a public health standpoint.

Food manufacturers have responded to the message that Americans need to increase their consumption of whole grains by adding whole grains to a broad array of their products in meaningful amounts. Where food manufacturers can make products 100% whole grain, they have often done so, producing whole grain brown rice, whole wheat bagels, whole wheat rolls, whole grain bread, whole grain croutons, whole grain crackers, whole grain cereals, and whole grain pasta. Food manufacturers have also incorporated whole grain pastas and rice into mixed dishes and frozen entrees.

But it is not feasible to make all whole grain-containing products 100% whole grain. In some cases there are technological barriers. For example, whole grain flour can influence the rheology of the dough and the sheeting process. In other cases, whole grains may negatively impact the texture, color, appearance, and taste of certain food products. For instance, whole grain flours can impart a bitter taste in some products and reduce certain flavors in others. Thus, food manufacturers may be able to add meaningful amounts of whole grains to their products, but may not be able to make a product that is 100% whole grain. Products with meaningful amounts of whole grains include bagels, breads, breakfast bars, breakfast cereals, cookies, energy bars, granola bars, pasta, pizza and pizza crusts, rolls, tortillas, and waffles.

To provide a data-based context for this discussion, GMA analyzed the whole grain content of the MyPyramid seven-day menus posted on the mypyramid.gov website and created sample menus for consumption of products with whole grains added at less than 100%. These menus were created using food products that are now in the marketplace, will be introduced, or could reasonably be introduced into the marketplace, based on reformulations by GMA member companies. Even more importantly,

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<sup>7/</sup> *Id.* Under the current framework provided by the *Dietary Guidelines*, this would mean that Americans are consuming less than 1 one ounce-equivalent of whole grains per day.

they are based on foods that are commonly consumed by large numbers of American consumers and which are reformulated so as to meet consumers' taste expectations. <sup>8/</sup> These sample menus, described in more detail below, illustrate how consumers can reach the daily recommendation of at least 48 grams of whole grains, with no or little contribution from products made with 100% whole grains, and can do so without consuming an inordinate number of calories. Thus, these whole grain containing foods would provide a viable option for meeting the *Dietary Guidelines* recommendation for those consumers who, for whatever reason, do not regularly consume 100% whole grain products.

This is the crux of the issue. GMA believes that FDA should recognize the validity of the concept that consumers can attain their daily recommended levels of whole grains, within a diet with an appropriate amount of calories, without relying exclusively (or substantially) on products with 100% whole grains. These new products by GMA members have the capacity to raise the level of whole grain consumption in this country very significantly—many times above the current estimates of less than 5% of Americans reaching the daily recommended levels of consumption. This is an opportunity for achieving real and significant public health gains. GMA members know which grain products Americans, both children and adults, regularly consume and are making a concerted effort to add whole grains to those products in meaningful amounts in ways which meet consumers' taste expectations. FDA should encourage food companies to convey that important information to consumers in clear and simple terms. When such information is conveyed, these whole grain containing products will enable consumers to eat foods which contribute to their overall intake of whole grains in important ways, and thus help implement the *Dietary Guidelines*' recommendation to “make half your grains whole.”

The key to this success is an FDA labeling policy that encourages communicating to consumers that these products contain meaningful amounts of whole grain, and to do so within the context of and the framework provided by the MyPyramid and *Dietary Guidelines* recommendations. Thus, label statements that place the quantitative amount of whole grains in the context of the daily diet, that link the amount of whole grains with MyPyramid, and that characterize the amount of whole grains present in a food with clear terminology, are fully consistent with the underlying goal to use the food label to implement the *Dietary Guidelines*. Such label statements will serve to benefit consumers and implement good

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<sup>8/</sup> For the menu modeling, foods were selected that reflect products from the top food sources of grain in U.S. diets (NHANES 1999-2002). Twenty-four of the top 50 grains sources were used in the menu modeling, including 7 of the top 10 grain sources.

dietary practices, and will do so in ways that meet the legal requirement of being truthful and non-misleading.

**I. FDA Should Encourage Manufacturers to Place Factual Statements about Whole Grain Content in Context on the Food Label, and to Expressly Link the Amount of Whole Grains to MyPyramid**

As we raise consumer awareness of the importance of including whole grains in their diet they don't always know how to do so. More importantly, consumers cannot always remember how much whole grains they should consume. The value of the information provided by label statements declaring the amount of whole grains present in grams can be enhanced if consumers are also provided with the context to understand the significance of the amount of whole grains in a particular product in relation to the daily diet. Accordingly, one effective way to implement the *Dietary Guidelines* and help make certain that Americans consume sufficient amounts of whole grains is to provide information on the food label contextualizing the amount of whole grains provided by a food product within the framework established by MyPyramid and the *Dietary Guidelines*.

FDA's Draft Guidance would permit manufacturers to make factual statements about whole grains in their products, such as "100% whole grain" or "10 grams of whole grains," provided that the statement is not false or misleading. For statements quantifying the amount of whole grains (e.g., "10 grams of whole grains"), however, FDA should encourage manufacturers to accompany that statement with a clarification providing consumers with the proper context for understanding how the declared amount of whole grains compares with the recommended daily amount under the *Dietary Guidelines* and MyPyramid. Thus, FDA should amend its guidance to encourage statements such as: "10 grams of whole grains: at least 48 grams of whole grains are recommended daily." This would provide consumers with critical information needed to understand the significance of the quantitative declaration within the context of the total daily diet.

In addition, manufacturers should be encouraged to link, on the food label, the amount of whole grains in a product to the recommendations contained in MyPyramid and the *Dietary Guidelines*. This can be accomplished through the optional inclusion of certain statements on the product. For example, "for a 2000 calorie diet you've consumed 1 one-ounce equivalent of whole grains of the suggested 3 one ounce-equivalents of whole grains. For more personalized nutrition information go to [www.mypyramid.gov](http://www.mypyramid.gov)." In a similar fashion, USDA's interim guidance suggests linking statements such as "whole grains = 2 one ounce-equivalents" with "USDA's MyPyramid recommends at least 3 one ounce-

equivalents of whole grains per day.” <sup>9/</sup> These types of optional statements would encourage consumer understanding of the recommendations for consumption of whole grains in MyPyramid and the *Dietary Guidelines*, and would provide another avenue for placing quantitative information into proper context for consumers. As such statements would enhance consumer understanding, they would in no way be false or misleading under Section 403(a) of the Federal Food, Drug and Cosmetic Act (FFDCA).

## **II. FDA Should Allow Manufacturers to Characterize the Amount of Whole Grains Present in Food Products**

As an additional means of encouraging whole grain consumption, FDA should allow food manufacturers to characterize the amount of whole grains present in food products, using terms such as “good source” and “excellent source.” The terms “good source” and “excellent source” are well understood by consumers as indicating products that provide dietarily significant amounts of a substance. FDA should draw upon these consistent and proven methods for educating consumers about food products to encourage consumers to obtain their whole grains from a greater variety of products and thus promote greater adherence to the *Dietary Guidelines*. In particular, FDA should revise the Final Guidance to exclude the statement that manufacturers may not make label statement that “imply a particular level of the ingredient (i.e. “high” or “excellent source”).” <sup>10/</sup> To the contrary, use of these terms would not be misleading, but rather will serve to provide consumers with truthful information that they can use to improve their dietary practices.

### **A. Classification of Whole Grains**

FDA has previously stated that the lack of a clear “classification” for whole grains is a limiting factor in considering whether to permit claims such as “good source” and “excellent source.” FDA should

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<sup>9/</sup> *Use of the USDA MyPyramid Reference on Meat and Poultry Labeling and Whole Grain Claims*, Food Safety and Inspection Service Statement of Interim Policy Guidance (Oct. 14, 2005).

<sup>10/</sup> *Draft Guidance on Whole Grain Label Statements*, Food & Drug Administration (Feb. 17, 2006), available at <http://www.cfsan.fda.gov/~dms/flragui.html> (last visited Apr. 17, 2006). At a minimum, FDA should delete this provision from the Final Guidance and permit food manufacturers to use these terms subject to the false or misleading standard.

take the opportunity to make such a determination in the Final Guidance on Whole Grain Label Statements.

In FDA's response to a citizen petition requesting that FDA develop definitions for "excellent source" and "good source," the agency posed four options for classifying whole grains: "food category, food ingredient, nutrient, or something else." <sup>11/</sup> Rather than create a new classification for whole grains (i.e., "something else"), it would make sense to find the most reasonable place for whole grains within the existing classification framework. In this respect, GMA believes that whole grains are most like an ingredient. Although grains in general are a food category, whole grains are a subset of that category, not a category themselves. Moreover, although whole grains are a major source of the nutrient fiber, they are more than just fiber and, therefore, are not properly classified as a nutrient, either. As the agency has previously recognized, "the health benefits of whole grains are based on more than their fiber content." <sup>12/</sup>

Accordingly, the "best fit" is to classify whole grains as an ingredient. As FDA currently points out in the draft guidance, the term "whole grain" is simply another way of describing the bran, germ, and endosperm. In essence, it is a collective term describing a "single food (e.g., wild rice, popcorn), or . . . an ingredient in a multi-ingredient food (e.g., in multi-grain breads)." <sup>13/</sup> Like other ingredients, whole grains can be added, and are being added, to various foods. Also like other ingredients, whole grains are a source of beneficial nutrients, just like certain oils are a source of poly or mono-unsaturated fat and milk is a source of calcium. Finally, the presence of whole grains in food can be ascertained from the ingredient statement on the food label, not from the Nutrition Facts Panel.

Categorizing whole grains as an ingredient maintains consistency with the existing health claims for whole grains. <sup>14/</sup> The

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<sup>11/</sup> Letter to Stuart Pape, Patton Boggs, from Margaret O'K. Glavin, Associate Commissioner for Regulatory Affairs, Food and Drug Administration (Nov. 8, 2005).

<sup>12/</sup> Letter to Judi Adams, Grain Foods Foundation, from Shellee Anderson, Food Labeling and Standards Staff, Food and Drug Administration (Jan. 24, 2006).

<sup>13/</sup> *Dietary Guidelines for Americans, 2005* 28, available at <http://www.health.gov/dietaryguidelines/dga2005/document/> (last visited Apr. 17, 2006).

<sup>14/</sup> For example, FDA has not objected to the following claim: "Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat,

regulations for health claims explain that they characterize the relationship between a substance and a disease or health related condition. “*Substance* means a specific food or component of food . . . .” <sup>15/</sup> In addition to being consumed as ingredients in other foods, whole grains are specific foods, which may be consumed by themselves (e.g., popcorn, brown rice). In this way, whole grains are similar to nuts, which also may be consumed in the diet as specific foods or as ingredients. Thus, the term substance encompasses ingredients – the two are not mutually exclusive. <sup>16/</sup>

In sum, whole grains are best classified as an ingredient. They function as an ingredient in many foods and are a valuable constituent in a wide variety of products. Thus, FDA should take the opportunity presented by the Final Guidance to classify whole grains by categorizing them as an ingredient.

**B. The Best Communication Tools to Encourage Increased Consumption of Whole Grains are the “Good Source” and “Excellent Source” Terms**

In order to decipher the information they receive regarding how to make sound dietary choices, consumers need straightforward terms to guide food product selection. Nowhere is this more important than for communications regarding the nutritional and health benefits of whole grains. Because the “good source” and “excellent source” terms are understandable and familiar, they are particularly suited for use with whole grains to help consumers identify foods that can provide significant amounts of whole grains to help them meet the recommendations of the *Dietary Guidelines*.

Other label statements, such as 100% whole grain statements, are useful, but limiting. As previously discussed, it is not technologically feasible or commercially prudent to make all products 100% whole grain.

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and cholesterol, may help reduce the risk of heart disease and certain cancers.” See *Health Claim Notification for Whole Grain Foods* (Jul. 1999), available at <http://www.cfsan.fda.gov/~dms/flgrains.html> (last visited Apr. 17, 2006).

<sup>15/</sup> 21 C.F.R. 101.14(a)(2).

<sup>16/</sup> Indeed, were FDA to classify whole grains as a substance rather than as an ingredient, as a basis for permitting “good source” and “excellent source” label statements for whole grains, GMA would support such a determination, as the definitions of ingredients and substances are very close and, in many ways, overlapping.

Those products which contain less than 100% whole grains still provide meaningful nutritional and health benefits to consumers. Importantly, these products satisfy the taste preferences of larger numbers of Americans. <sup>17/</sup> Thus, if provided with the right information, many consumers are more likely to choose foods with meaningful amounts of whole grains and gain an important part of the benefits that 100% whole grain products provide.

Most importantly, there is nothing in the FFDCA that prohibits use of the terms “good” or “excellent” in connection with substances other than nutrients. As these terms are familiar to consumers as indicators of foods that provide a significant amount of the identified substance, they can provide the contextual information that consumers need to make sound choices about whole grains. These terms would explain the amount of whole grains present in a food in a way that relates to total dietary consumption and would enable consumers to choose from a variety of products with meaningful amounts of whole grains, rather than only those which are 100% whole grain. In this way, food manufacturers will be able to help Americans implement the recommendations of the *Dietary Guidelines*.

**C. Descriptive Whole Grains Claims Can be Used Effectively in Ways that are Truthful and Non-Misleading**

GMA believes that descriptive claims such as “good source” and “excellent source” can be used effectively with products containing whole grains. As already expressed, these are straightforward terms with which consumers are familiar, and they are proven communication tools. Additionally, there are two ways by which the use of these terms could be enhanced to promote even greater consumer understanding. First, food manufacturers could use “good source” or “excellent source” on the food label and place that term in context of the daily diet and/or expressly link that information to the *Dietary Guidelines* and MyPyramid. Second, FDA could define “good source” and “excellent source” in the Final Guidance by utilizing the *Dietary Guidelines*’ recommendations to quantify whole grains consumption.

**1. Manufacturers Could Use “Good Source” or “Excellent Source” on the Food Label by Placing the Applicable Term in the Context of the Daily Diet and/or by Linking the Amount of Whole Grains to MyPyramid**

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<sup>17/</sup> As consumers learn to accept the taste of whole grain products, food manufacturers would have an incentive to increase the amounts of whole grains provided in those foods.

Just as quantitative statements regarding the amount of whole grains present in a food can be enhanced through the use of contextual information, so, too, can statements like “good” or “excellent source” of whole grains be made informative (and not false or misleading) through the use of similar information. In conjunction with stating “good source” or “excellent source of whole grains,” manufacturers could explain on the food label why the product is a “good source” or “excellent source” by stating the amount of whole grains provided and/or by linking that amount to the recommendations made by the *Dietary Guidelines*. For example, a product may provide the following information: “Good [or excellent] source of whole grains. Contains X grams of whole grains. At least 48 grams of whole grains are recommended daily.” In a similar fashion, a food label may declare: “Good [or excellent] source of whole grains. Provides X one ounce-equivalent(s) of whole grains. MyPyramid suggests 3 one ounce-equivalents of whole grains per day for a 2,000 calorie diet.”

In this manner, use of the “good” and “excellent” source terms would not be false or misleading because consumers would be provided with contextual information to properly understand why a particular food product is a good or excellent source of whole grains.<sup>18/</sup> Equally important, this information would help the consumers understand the product’s role and placement within the daily diet. Moreover, this information would promote adherence to the *Dietary Guidelines* and would encourage consumers to obtain personalized dietary information from MyPyramid. As such, “good source” and “excellent source” terms can be used effectively to promote the consumption of products containing meaningful amounts of whole grains.

As explained in more detail below, it is important to emphasize that use of the “good source” and “excellent source” terms is subject to the false and misleading standard under Section 403(a) of the FFDCA—not the structure and definitions applicable to nutrient content claims under Section 403(r). By placing the “good source” and “excellent source” terms in proper context, as described above, use of these terms would not be false or misleading. Accordingly, FDA should provide in the Final Guidance for use of “good source” and “excellent source” terminology when those terms are placed in proper context on the food label by manufacturers so as not to be false or misleading to consumers.

## **2. FDA Could Define “Good Source” and “Excellent Source” Claims for Use with Whole Grains**

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<sup>18/</sup> Additionally, FDA might choose to set minimum levels in the Final Guidance for “good” and “excellent” source as applied to whole grains. Options for setting those minimum levels are described below.

By drawing upon the *Dietary Guidelines*, the prerequisites for use of the terms “good source” and “excellent source” can be defined by FDA in a way that ensures that products bearing such label statements contain a meaningful amount of whole grains. While there is no “Daily Value” for whole grains, both MyPyramid and the *Dietary Guidelines* recommend that consumers eat at least 3 one ounce-equivalents of whole grains a day (or at least 48 grams), for a 2000 calorie diet. Thus, the amount of whole grains necessary in a food to qualify for a descriptive claim could be based upon these recommendations. In other words, FDA could use the MyPyramid “3 one ounce-equivalents” recommendation for whole grains as the functional equivalent of the Dietary Reference Intake (DRI) for nutrients. This provides the necessary predicate for deciding how much of added whole grains is a meaningful amount.

The *Dietary Guidelines* recommend the consumption of at least 3 one ounce-equivalents of whole grains per day. USDA has determined that because a slice of white bread contains 16 grams of flour, 1 one ounce-equivalent of whole grains contains 16 grams of grain. Accordingly, 3 one-ounce equivalents of whole grains would provide 48 grams of grain. [19/](#) Using this framework, GMA proposes two different options by which FDA could establish quantitative requirements for “good source” and “excellent source” claims and at the same time provide information to consumers that uses the ounce-equivalents metric established by MyPyramid. Under the first option, 5 grams of whole grains present in food per Reference Amount Customarily Consumed (RACC) and per labeled serving would qualify for a “good source of whole grains” claim, and 10 grams of whole grains present per RACC and per serving would qualify for an “excellent source of whole grains” claim. Under the second option, ½ ounce or 8 grams of whole grains per RACC and per labeled serving would qualify for a “good source” claim and 1 ounce or 16 grams of whole grains would qualify for an “excellent source” claim. The rationale for each option is discussed below.

These two proposals need to be evaluated in conjunction with the attached sample menus prepared by GMA. These menus provide examples of how these options would assist consumers in reaching the recommended goal of at least 48 grams of whole grains per day, as well as the resulting calorie intakes. As noted above, these menus are based on products that are now in the marketplace, will be introduced, or could reasonably be introduced into the marketplace, based on reformulations by

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[19/](#) Although different foods, such as brown rice and certain ready-to-eat cereals contain different amounts (in grams) of whole grains per “ounce equivalent,” GMA believes that bread constitutes the most reasonable benchmark, as recognized by USDA.

GMA member companies and represent foods that are widely consumed within the U.S. population. Thus, they provide a practical “roadmap” to achieving the recommendations of the *Dietary Guidelines* and MyPyramid.

**a. Five Grams and Ten Grams**

The first option – allowing those foods containing 5 grams of whole grains per RACC and per labeled serving to bear a “good source of whole grains” label statement, and to allow those foods containing 10 grams of whole grains per RACC and per labeled serving to bear an “excellent source of whole grains” label statement – would be based on the amounts that are consistent with the 10% and 20% requirements for nutrient content claims. That is, 10% of the minimum daily recommended amount of 48 grams is approximately 5 grams, and 20% of the minimum daily recommended amount of whole grains is approximately 10 grams. Just as in other contexts, 10% and 20% of the recommended minimum would be considered meaningful amounts.

At these levels, food manufacturers can add whole grains to a wide variety of foods, without adversely affecting their taste. Additionally, manufacturers would be able to add a meaningful amount of whole grains to foods with smaller RACCs. Consumers would have many more choices of food products that contain whole grains because food manufacturers will be encouraged to add whole grains to their products at these amounts. Although it can be challenging to reach the recommended daily level of 48 grams under this option, that level could be reached by replacing any one or more of the products with a 100% whole grain product. Consumers could consume 40 grams of the daily recommended 48 grams of whole grains from a mixture of products providing 5 grams and 10 grams and an average caloric contribution of 715 calories. Thus, implementation of “good” and “excellent source” claims for foods containing 5 grams or 10 grams of whole grains per RACC and per labeled serving would provide consumers with a plethora of whole grain containing products in order to more easily meet the minimum daily recommended amount of whole grain consumption.

**b. Eight Grams and Sixteen Grams**

The second option, 8/16 grams of whole grains for good/excellent source claims, is based on using the “ounce-equivalent” metric from the *Dietary Guidelines*/MyPyramid and converting that to grams. As noted above, using bread as a commonly consumed food that is suitable for containing whole grains, the conversion to grams would be 16 grams for 1 “one ounce-equivalent” and 8 grams for ½ “one ounce-equivalent.”

If the agency accepts the proposal that 8 grams of whole grains per RACC and per labeled serving or a ½ ounce equivalent of whole grains qualifies for a “good source” claim, consumers would be receiving 16% of the daily recommended amount for whole grains. Likewise, 1 ounce or 16 grams of whole grains represents 33% of the daily recommended amount of whole grain consumption. Both are significantly more than the 10% and 20% requirements for nutrient content claims and would even more clearly be considered meaningful amounts.

Additionally, products with whole grains at these respective amounts will contribute significant nutritive benefits to consumers, within a reasonable level of caloric consumption. For example, as evidenced in the attached menus, consumers could meet the minimum *Dietary Guidelines* recommendation of 48 grams per day by consuming foods containing 16 grams of whole grains, with an average caloric contribution from the whole grains of 387 calories or by consuming a mixture of products containing at least 8 grams of whole grains and products containing 16 grams of whole grains, with an average caloric contribution from the whole grains of 580 calories. Thus, implementation of “good” and “excellent source” claims at these levels would promote the consumption of whole grain products in a manner consistent with good dietary practices.

In sum, either through manufacturer declarations providing contextual information for descriptive terms and/or through agency determined quantitative requirements, terms such as “good source” and “excellent source” can be used to describe products containing whole grains in an effective and meaningful way. Tied with the increasing number of products that are being made available to consumers—as made clear by the sample menus provided by GMA—use of the “good source” and “excellent source” terms could greatly assist consumers in making “half [their] grains whole” while still maintaining reasonable caloric intake levels.

### **3. Use of “Whole Grain” in as Characterizing Term in Product Name**

In the Draft Guidance, FDA stated that “we recommend that pizza that is labeled “whole grain” or “whole wheat” only be labeled as such when the flour ingredient in the crust is made entirely from whole grain flours, or whole wheat flours, respectively.” [20/](#) This would create a

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[20/](#) *Draft Guidance on Whole Grain Label Statements*, Food & Drug Administration (Feb. 17, 2006), available at <http://www.cfsan.fda.gov/~dms/flragui.html> (last visited Apr. 17, 2006). This statement in the Draft Guidance would have the effect of applying existing criteria for standardized foods to non-standardized foods as well. Not only is this inappropriate—as non-standardized foods have always had

disincentive for food manufacturers to add meaningful amounts of whole grains to products, like pizza, which are widely consumed by the population. As the agency is well aware, consumers do not consume enough whole grains. Thus, as noted above, FDA ought to encourage producers to add whole grains to products in meaningful amounts, even if not at the 100% level. [21/](#)

FDA should revisit this issue and should consider permitting those products with meaningful amounts of whole grains to use the term “whole grain” or “whole wheat” in the product name of the food, so long as the label, in its entirety, is not false or misleading. Use of these terms should not be considered inherently inappropriate, as there are certain circumstances under which a particular label, when viewed in its entirety, would not be false or misleading to consumers. As FDA revises its guidance, the agency should consider several different means by which companies can ensure that only those products which would contribute a meaningful amount of whole grains to the diet could be described as a whole grain product.

For example, FDA could allow those foods providing at least a “good source” of whole grains to use the terms “whole grain” or “whole wheat” as a characterizing term in the product name. Similarly, FDA could permit the use of these terms with those products whose grain content is at least 51% whole grain. Alternatively, FDA could adopt a framework similar to that adopted by the Food Safety and Inspection Service (FSIS) of USDA whereby FSIS will not object to the use of descriptors such as “whole wheat pasta” for those food components that are not subject to a standard of identity and in which at least 51% of the grain components are whole grain (and which have a minimum of 8 grams of whole grains). [22/](#) No matter

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more flexibility in product names than do standardized foods—but doing so through a Guidance Document is procedurally improper and creates due process issues.

[21/](#) For example, most commercial pizza dough contains vital wheat gluten. Thus, while it is not possible for the dough to be 100% whole grain, food manufacturers can, nonetheless, manufacture a product containing a meaningful amount of whole grains.

[22/](#) FSIS has also stated that there should be a significant amount of the whole grain component (at least a one-half ounce-equivalent or 8 grams of dry whole grain ingredient per labeled serving and per RACC) and generally more whole grain than refined grain in the product. *Use of the USDA MyPyramid Reference on Meat and Poultry Labeling and Whole Grain Claims*, Food Safety and Inspection Service Statement of Interim Policy Guidance (Oct. 14, 2005).

which option is chosen by FDA, GMA would support a policy under which the label of a product whose identity statement included the characterizing terms “whole grain” or “whole wheat” would disclose the amount of whole grains provided. [23/](#) Such a disclosure should accompany the product name on the food label so that the consumer can readily determine the amount of whole grains added. In this way, use of these terms in the product name of certain foods would not be misleading.

#### **4. Descriptive Terms are Not False or Misleading**

In the past, FDA has expressed its concern that statements like “excellent source of whole grains” are implied nutrient content claims and thus are prohibited. [24/](#) These issues were raised at a time when whole grains were considered to be valued solely because their contribution of fiber to the diet. Well over a decade later, we now know that whole grains contribute more to the diet than simply supplying fiber. As previously discussed, whole grains are not a nutrient. Accordingly, Section 403(r) of the FFDCA is inapplicable and the use of “good source” and “excellent source” is not inherently inappropriate. Instead, these claims should be evaluated according to the false and misleading standard imposed by Section 403(a) of the FFDCA.

Additionally, the *Dietary Guidelines* have also changed over that period of time. Currently, the *Dietary Guidelines* recommend that Americans should consume at least 3 one ounce-equivalents of whole grains per day. And as noted earlier, today’s scientific knowledge attributes the health and nutritional benefits of whole grains to go well beyond just that of fiber. Thus, far from being misleading or inappropriate, the use of “good source” and “excellent source” would promote adoption of the *Dietary Guidelines* by consumers and encourage consumption of whole grains. The use of “good source” and “excellent source” should not be, and is not required to be, reserved solely for nutrient content claims. FDA should “use

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[23/](#) In addition, declarations of the amount of whole grains in a product identified as “whole grain,” could also be linked to explanatory statements such as “at least 48 grams of whole grains are recommended daily.”

[24/](#) Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2374 (Jan. 6, 1993). Notably, in the Draft Guidance, FDA did not explain why the use of “excellent source” and “good source” is inherently misleading. If FDA has a factual basis for this determination, that information should be available for public comment.

what works” in order to promote adherence to the *Dietary Guidelines*. Through the use of these commonly understood terms, consumers will understand that they will not obtain all of their recommended whole grain intake from one product, but rather that the product can play a specific role in meeting their dietary goals. Use of these terms would, therefore, easily pass muster under the false and misleading provision of the FFDCA.

In sum, the terms “good source” and “excellent source” are well recognized and understood by consumers. Applying terms with which consumers are already familiar will prevent consumer confusion, not create it. Given our new knowledge regarding the role that whole grains play in the diet and the success of the “good source” and “excellent source” terms, FDA can feel confident that application of these terms to foods containing less than 100% whole grains would not be misleading.

### **III. The Definition of Whole Grain as Applied to Barley Should be Modified to Allow for Minimal Processing Needed for Human Consumption.**

FDA should modify the Draft Guidance on Whole Grain Label Statements regarding barley as a whole grain. As written, the guidance effectively precludes all barley, because some minimal processing is needed to make it useable in food for human consumption and nutritionally bioavailable. The Final Guidance should clarify that that barley, to qualify as a whole grain, should be processed at the minimum amount needed to maintain, as close as possible, the same ratio of bran, germ, and endosperm as is found in the intact caryopsis.

While recognizing that Americans fail to consume a sufficient amount of whole grains, the agency in effect excludes a potential source of whole grains from entering their diets. Without the ability to market or label pearled barley containing products as whole grain, manufacturers will not be able to encourage their consumption. FDA should not limit the options available to Americans wishing to follow the *Dietary Guidelines*.

Additionally, FDA’s decision is contrary to common assumptions regarding barley. For example, in a study recently conducted by the Agricultural Research Services of USDA, researchers specifically provided the study’s subjects with pearled barley as part of their servings of whole grains. [25/](#) Likewise, the 2000 Dietary Guidelines listed pearl barley

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[25/](#) Marcia Wood, “Whole Grain Foods’ Fat Fighting Role Scrutinized.” *Agricultural Research Service* 20 (March 2006).

as a way for consumers to increase their intake of whole grain foods. [26/](#) Finally, pearl barley, a dry milled barley grain product, is an appropriate source of beta-glucan soluble fiber and is eligible to bear a health claim on the relationship between beta-glucan fiber and reduced risk of coronary health disease. [27/](#) As such, FDA's decision to exclude pearled barley from the definition of whole grain should be re-evaluated.

## **CONCLUSION**

Whole grains are an important part of the diet, and Americans need to be consuming much more of them. As such, FDA should facilitate communication to consumers about which products contain a meaningful amount of whole grains, even if those products are not 100% whole grain. To accomplish this, FDA should:

- Recognize that consumers can attain the recommended consumption of whole grains through products which contain less than 100% whole grains. The new sample menus provided by GMA illustrates just how feasible it is for consumers to achieve the daily recommendations with foods containing whole grains at these levels.
- Encourage factual, quantitative statements of whole grain content to be placed in the context of the recommended consumption of at least 48 grams of whole grains daily and/or to be linked to MyPyramid.
- Recognize that whole grain claims are regulated under the prohibition on false or misleading labeling in the FFDCA and are not subject to the regulations applicable to nutrient content claims.
- Recognize the broad consumer understanding of “good source” and “excellent source” terms and facilitate their appropriate use on foods containing meaningful amounts of whole grains.
- Allow the term “whole grain” or “whole wheat” as a characterizing term in the product name (e.g., whole grain pizza) of certain foods.

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[26/](#) *Nutrition and Your Health Dietary Guidelines for Americans, 2000*, available at <http://www.health.gov/DietaryGuidelines/dga2000/document/build.htm#grains> (last visited Apr. 10, 2005).

[27/](#) Food Labeling: Health Claims; Soluble Dietary Fiber from Certain Foods and Coronary Heart Disease, 70 Fed. Reg. 76150, 76155 (Dec. 23, 2005).

- Modify the definition of whole grains as it pertains to barley.

By providing companies with an incentive to add meaningful amounts of whole grains to their products and by giving consumers a clear way to understand the significance of the amount being added, FDA would greatly advance the health of American consumers.

Accordingly, GMA urges FDA to revise the Final Guidance on Whole Grain Label Statements in these important ways. These recommendations are a logical outgrowth of FDA's Draft Guidance and thus can be provided in the Final Guidance under FDA's authority to prevent false and misleading food labeling statements.

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Please contact us if GMA can assist the agency with additional information or perspectives that may be helpful as the agency revisits this issue.

Sincerely,

A handwritten signature in black ink that reads "Alison J. Kretser". The signature is written in a cursive style with a long, sweeping underline.

Alison J. Kretser  
Senior Director  
Scientific and Nutrition Policy  
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