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

RE: Docket No. 2006D-0066; Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements

General Mills, Inc., submits these comments regarding the Food and Drug Administration's (FDA) Draft Guidance for Whole Grain Label Statements. General Mills is a Delaware Corporation with its general offices at No. 1 General Mills Boulevard, Minneapolis, MN 55426. General Mills is a major packaged-food manufacturer engaged for over 75 years in the development and production of food products including flour, ready-eat-cereals, refrigerated dough products, cake and other dessert mixes, soups, vegetables, snacks and numerous other products.

Summary of Main Points

As will be discussed in greater detail below, General Mills applauds FDA for taking this first step toward providing clear and consistent communication regarding whole grain. General Mills agrees that truthful and nonmisleading label statements allowing consumers to identify easily products that contain significant amounts of whole grain are useful to the consumer, and should be encouraged. In that regard, General Mils recommends the following amendments to FDA's draft guidance document:

- Factual, quantitative statements of whole grain content should be placed in the context of the daily recommended amount of whole grain (at least 48 g) so that such statements are not confusing or misleading to consumers.
- Descriptors that are simple to understand and familiar to consumers, such as "good" ($\geq$ 8g/serving) and "excellent" ($\geq$ 16g/serving) source of whole grain, should be encouraged to help consumers identify foods with dietarily significant amounts of whole grains.
- The characterizing term, "whole grain" (or the specific whole grain) is appropriate in product names when products contain a meaningful amount of whole grain, but less than 100 percent.
- Lightly pearled barley should be considered a whole grain.

Background

General Mills has a long-standing history of developing products containing whole grain and encouraging the inclusion of whole grain in the diet. From the introduction of Wheaties 100 percent whole grain cereal over 80 years ago, to the development of a health claim for whole grain products in 1999, General Mills has been a strong advocate

of the benefits of whole grain. To further encourage the consumption of whole grain, General Mills petitioned the Agency in 2004 to develop definitions for the terms "good source" and "excellent source" to describe dietarily significant amounts of whole grains. (Dkt. No. 2004P-0223/CP-1, filed May 11, 2004) These terms can assist consumers in identifying products that provide meaningful amounts of whole grain. Subsequently, the 2005 Dietary Guidelines for Americans recommended that Americans consume at least three one-ounce equivalents of whole grain per day. The label terms and related definitions General Mills proposed in our petition fit squarely with that recommendation, and would have enabled consumers to easily identify those foods that would assist them in meeting the recommendation in the Dietary Guidelines.

In November 2005, FDA responded to our petition, stating that the petition raised several broader questions that the Agency needed to address prior to ruling on the requested whole grain descriptors, and noted that the Agency would likely seek public comment and issue guidance regarding the definition of whole grain. FDA then issued its Draft Guidance on February 17, 2006. FDA's draft guidance proposes a definition of "whole grain," as well as provides guidance around the types of label statements that the Agency considers appropriate to describe the whole grain content of a food.

While General Mills certainly applauds FDA's first steps in this area, and agrees that all label statements regarding whole grain content must be truthful and nonmisleading, we believe that some of the statements in the Draft Guidance will not serve the purpose of benefiting the consumer, and could even discourage terms that could be very useful to the consumer. With the changes described below, however, FDA could provide useful guidance to industry that would serve the dual purpose of allowing companies to communicate to consumers about the whole grain content in their products, as well as provide consumers with a useful tool to identify easily those products that will make a meaningful contribution to the recommended daily intake of whole grain.

General Comments

As FDA acknowledges in the draft guidance, for years the Federal Government has worked to provide consistent and scientifically-sound dietary advice to consumers. In concert with the growing body of scientific evidence showing positive health effects of diets rich in whole grain, the 2005 Dietary Guidelines recognize the benefits of whole grain and for the first time recommend a specific level of consumption daily (3 or more ounce-equivalents of whole grain daily for most adults). In particular, the recommended level of whole grain ranges from 3 to 5 ounce-equivalents for diets containing from 1600 to 3200 calories.

The recommendation of 3 or more one ounce-equivalents of whole grain equates to at least 48 g of whole grain daily. The USDA defines a "grain serving" or "one ounce-equivalent" as the "grams of grain product containing 16 g of flour."[1], [2] Accordingly, an

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[1] U.S. Department of Health and Human Services and U.S. Department of Agriculture. *Dietary Guidelines for Americans 2005*. 6th Edition, Washington, DC: U.S. Government Printing Office, January

ounce-equivalent of whole grain would contain 16 g of whole grain and three ounce-equivalents would provide at least 48 g of whole grain.

As set forth in greater detail in the Appendix to these comments, recent scientific studies also support the consumption of at least 48 g of whole grain daily with health benefits, such as reduced risk of cardiovascular disease, observed when intakes of whole grain reach at least 43-50 g daily.

The Dietary Guidelines acknowledge that the benefits of whole grain go beyond its fiber contribution to functions including weight management, reduction of certain chronic diseases, and provision of nutrients such as several B vitamins, iron, magnesium and selenium. With the increased emphasis on whole grains in the new Dietary Guidelines, consumers have more interest in whole grain foods and are looking for ways to identify and incorporate such foods into their diets.

Although research shows that consumers believe that whole grains confer important nutritional and health benefits, the overwhelming majority of Americans do not consume adequate amounts of whole grains. Nine in ten Americans fail to consume the recommended amount of whole grains daily, with most adults consuming on average <1 serving (one, one-ounce equivalent) daily (NHANES 1999-2000). To assist consumers in the identification and selection of whole grain products, food manufacturers need meaningful ways to communicate dietarily significant amounts of whole grain on food labels.

As noted above, General Mills applauds FDA for taking the first step of issuing a draft guidance. Clear and consistent label statements would also incent manufacturers to include meaningful amounts of whole grain in a greater variety of food products. FDA should seek ways to encourage food manufacturers to include significant amounts of whole grain in their products, and thus assist consumers in meeting their recommended whole grain intake. FDA can facilitate whole grain communication by encouraging the use of truthful and non-misleading label statements, including statements that may describe a particular level of whole grain. These statements should include terms with

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2005. *Appendix A-2: USDA Food Guide describes the following as quantity equivalents for the grain group: "The following each count as 1 ounce-equivalent (1 serving) of grains: 1/2 cup cooked rice, pasta, or cooked cereal; 1 ounce dry pasta or rice; 1 slice bread; 1 small muffin (1 oz); 1 cup ready-to-eat cereal flakes."*

2 U.S. Department of Agriculture, Agricultural Research Service, 1997, Pyramid Servings Data: Results from USDA's 1995 and 1996 Continuing Survey of Food Intakes by Individuals. Section 3. Methodology; Development of the Pyramid Servings Database, available at: http://www.ba.ars/usda/gov/cnrg/services/section3.pdf (at 3-13). *The standard used for defining the amount of flour in one grain serving was one regular slice of commercial white bread (26 grams). This standard grain serving contained 16 grams of flour. Thus, one serving was defined as the grams of grain product containing 16 grams of flour. For products containing grain ingredients other than flour and products containing more than one grain ingredient, servings were calculated by summing grain servings from each grain ingredient. When reasonably standardized serving sizes were not described in the Pyramid, ARS calculated servings based on the grain content of the food.*

which consumers are familiar, such as “good source” and “excellent source,” should be applied clearly and consistently across the industry, and should provide the context of how the food contributes to the recommended daily whole grain level.

Consumers have made clear that they desire to increase their intake of whole grain, but have also made clear that it is difficult to identify foods that will help them achieve this goal.[3] For that reason, any label communication around whole grain content should primarily be focused on making it easier and simpler for consumers to identify foods that contribute dietarily significant amounts of whole grain. Clear, consistent, and simple statements around whole grain content will best serve this purpose.

Factual statements

General Mills believes that the Draft Guidance does not provide sufficient flexibility around label statements to allow manufacturers to accurately and appropriately communicate whole grain content that will assist consumers in meeting recommended whole grain intakes. Among options for communicating whole grain content on food labels, the draft guidance lists factual statements such as “100% whole grain” or “10 grams of whole grains,” provided that they are not false or misleading.

General Mills agrees that statements quantifying the amount of whole grain (e.g., “x grams whole grains”) may provide useful information to consumers, but believe they require further clarification to prevent them from being confusing and potentially misleading. We believe quantitative declarations of whole grain content should be allowed only if they are made in relation to the recommended daily intake.

Presently, major food manufacturers are making claims about whole grain content with as little as 2 g per serving, to up to or more than 48 g per serving. This disparity in the levels of whole grain content being portrayed as meaningful on food labels has the potential to cause confusion unless such statements are made within the context of recommended daily intake. Without reference to the recommended daily amount, these statements may not truly help consumers achieve or understand recommended whole grain intakes.

Thus, FDA should amend its guidance to require that factual statements of quantitative amounts of whole grain explicitly state, for example “X grams of whole grains; at least 48 grams of whole grains are recommended daily.”

Statements that describe a particular level of the ingredient

General Mills wholeheartedly agrees that any label statement regarding whole grain content must be truthful and nonmisleading. General Mills does not agree, however,

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[3] On-line survey of 1,804 consumers (nationally representative sample) conducted by Harris Interactive in December 2005

that statements that may describe a particular level of whole grain are not appropriate. In fact, these statements may be the most useful statements to consumers, and should be encouraged as tools that help consumers easily and quickly identify products that make meaningful contributions to the recommended whole grain intake. Consumers and health professionals, alike, are familiar with the terms "good" and "excellent" source and are accustomed to seeing them on food labels connected to product benefits.

General Mills continues to believe, as stated in our petition, that the terms "good source" and "excellent source" are the most effective and meaningful ways to communicate to consumers about foods that contain dietarily significant amounts of whole grain. For these terms to achieve maximum utility, and avoid consumer confusion, they should be applied consistently and uniformly across the industry. That is why General Mills asked FDA to define these terms as indicating that the food contains, respectively, at least 8 grams and at least 16 grams of whole grain per serving, so that consumers could be confident that whenever the terms appeared on food labels that food provided a meaningful amount of whole grain.[4] These amounts, as explained above, correspond to one half ounce equivalent and one ounce equivalent of whole grain, thereby allowing consumers to easily satisfy their whole grain recommended intake within the allotted grain servings, thereby not exceeding their caloric intake from grain products.

Because the Agency has stated that it must resolve other broader issues prior to defining these terms, it is now up to the manufacturers to provide information to consumers explaining what these terms mean. Currently, it is possible for manufacturers to define these terms differently, potentially leading to consumer confusion. For maximum utility, these terms should have a consistent definition, and should only be used when the food provides a meaningful amount of whole grain, at least 8 grams per serving. The terms "good" or "excellent" source should also be placed in context of the overall dietary contribution. This can be achieved by including quantitative information about the level of whole grain in the food, and the recommended amount of whole grain daily (at least 48 grams).

FDA should encourage, not discourage as the draft guidance currently does, these truthful and nonmisleading statements. Use of these terms enables manufacturers to truthfully convey their whole grain content, and makes it easier for consumers to identify foods that provide meaningful amounts of whole grain and meet Dietary Guidelines or MyPyramid recommendations; recommendations supported by both USDA and DHHS.

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[4] USDA's Food Safety and Inspection Service (FSIS) concurs that 8 grams denotes a meaningful amount of whole grain. In its Interim Policy Guidance "Use of the USDA *MyPyramid* Reference on Meat and Poultry Labeling and Whole Grain Claims," FSIS states that for foods to bear the terms "whole wheat" or "whole grain" "there should be a significant amount of whole grain component" and that "a significant amount of whole grain would be at least a one-half ounce equivalent of whole grain ingredient, i.e., at least 8 grams of dry whole grain ingredient."

The levels we propose for "good" (≥8g per serving) and excellent source (≥16g per serving) not only are dietarily significant, but are also achievable in terms of product formulation. Currently in the marketplace, there are numerous products containing at least 8g to more than 48g of whole grain per serving. These products cut across several food categories from pasta and rice, to cereals and snack bars, to cookies, crackers and snack chips, tortillas and popcorn.

General Mills also notes that there is nothing in the Federal Food, Drug, and Cosmetic Act (FDCA) or FDA's implementing regulations authorizing FDA to restrict the use of these terms when used in relation to whole grains. Under the FDCA and FDA's implementing regulations, the agency is authorized to regulate terms such as "high" or "excellent source" only with respect to claims about "nutrients." (21 U.S.C. 403(r)(1)(A); 21 C.F.R. 101.54.) It is well-known that whole grains are more than just fiber, as FDA itself has acknowledged.[5] Further, FDA has recognized the benefits of whole grains as distinct from those provided by fiber by allowing a health claim for whole grain foods and reduced risk of heart disease and certain cancers in addition to comparable health claims for fiber.[6]

FDA's legal authority with respect to non-nutrient claims, including whole grain claims is limited to prohibiting claims that are false or misleading. As Dr. Schneeman acknowledged during the press conference, claims characterizing the level of whole grains in a food cannot be deemed false or misleading -- and therefore prohibited -- as a class, but would need to be evaluated on a case-by-case basis in the overall context of the individual package. Accordingly, the FDCA misbranding provisions do not authorize FDA to ban "high" or "excellent source" claims for whole grains categorically, for such claims can be made in a manner that is truthful and nonmisleading. General Mills is proposing just such a manner by suggesting that the terms "good source" and "excellent source" be accompanied by quantitative information of the whole grain content of the food, and the minimum daily recommended amount of whole grain. FDA should encourage, not discourage, truthful and nonmisleading statements such as these.

Specific Comments

Question 1: What factors should be considered in determining whether a food is a whole grain?

We agree with the definition of whole grain put forth by FDA in the draft guidance. This definition is consistent with that from the American Association of Cereal Chemists

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[5] January 24, 2006 letter from Shellee Anderson, Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition, to Judi Adams, President, Grain Foods Foundation.

[6] Given this acknowledgment of the benefit of whole grain distinct from the fiber content, the agency therefore cannot maintain that claims characterizing the level of whole grains in food are implied fiber nutrient content claims. Because whole grain claims are not nutrient content claims, FDA lacks legal authority to regulate the use of terms such as "high" or "excellent source" in whole grain claims.

International (AACC). We believe this definition provides a scientific and practical framework for ingredient and food manufacturers to evaluate whether or not a grain is a whole grain, without being overly prescriptive or detailed in the requirements.

Question 2: What are some examples of cereal grains?
We concur with the list of cereal grains in the draft guidance. We recommend that FDA clarify that this list serves to provide examples of cereal grains and is not all inclusive.

Question 3: Should soybeans and chickpeas be considered whole grains?
We agree that legumes, oilseeds and roots should not be considered whole grains, including soybeans and chickpeas.

Question 4: Should a corn flour or corn meal made from corn grain to which the pericarp has been removed be considered whole grain?
We agree that corn flour that has had all the pericarp removed is not whole grain. However, nixtimalization of corn (treatment with lime) can result in varying amounts of pericarp that remain. An AACC expert task force is evaluating this corn processing approach to determine what degree of nixtimalization fits within the FDA whole grain definition. This is an important determination because nixtimalized corn products can contribute significantly to whole grain intake.

Question 5: Barley has a particularly tough hull and is often pearled to make it easier to cook and digest. Can the hull and perhaps a small amount of the bran attached to the hull be removed from barley in the pearling process and it still be considered a whole grain?
We support FDA's determination that pearled barley specifically should not be classified as whole grain. We do, however, believe that lightly pearled barley (naked, hulless or hulled barley) should be classified as a whole grain because it retains a majority of the bran, with the endosperm and germ intact. This minimal processing is necessary for barley to be safely consumed by humans. With the low intake of whole grains in the US diet, it is critical to include a wide range of whole grains, especially those that are typically consumed throughout the day in main dishes and soups.

Question 6: Should rolled oats be considered a whole grain?
We agree that rolled oats should be considered whole grain, along with other forms of whole grain oats and whole grain oat flour.

Question 7: Does the term "whole grain" mean the same as "100 percent whole grain?" If a product is labeled "whole wheat bagel" or "whole wheat pizza," how much whole wheat should it contain? What is graham flour?
We disagree that it is inappropriate for foods like pizza, bagels, crackers, etc., to be labeled "whole wheat" or "whole grain" only when made entirely from whole grain flours.

We believe it is appropriate for products with meaningful amounts of whole grains to use the term "whole grain" in the product name as long as the food label, in its entirety, is not false or misleading to consumers.

As noted earlier, consumers fall far short of meeting recommended intakes of whole grain. Describing products as “whole grain” when they contain dietarily significant amounts of whole grain (e.g., at least 51% of the grain ingredients are whole grain, or the food provides at least 8 grams of whole grain), even if not at the 100% level, incents manufacturers to add meaningful amounts of whole grain to products like pizza and bagels that are commonly consumed by consumers. This in turn, will help consumers better meet recommended intakes of whole grain.

FDA’s recommendation in the draft guidance would have the effect of extending the standard of identity for “whole wheat bread, rolls and buns” as defined in 21 CFR 136.180 to other products like pizza and bagels. The creation of new food standards goes beyond the scope of guidance documents and would require separate rulemaking. We oppose the development of new food standards for whole grain products and believe that our proposed options allow for the use of “whole grain” in product names without being misleading to consumers. Furthermore, these options will encourage manufacturers to incorporate whole grain into common foods and thereby increase consumers’ consumption of whole grains.

Question 8: What is durum wheat? Is it 100% whole grain? What products are made from durum wheat?
We agree that whole durum wheat is a whole grain, and suggest the use of label designations such as ‘whole durum wheat flour’ on the ingredient statement to help the consumer know that the product is whole grain.

Question 9: Are there standards of identity for products made from whole grains?
General Mills agrees that there is no standard of identity for “whole grains” per se. General Mills also agrees that some standards of identity, such as whole wheat bread, do exist that apply to whole grain foods. As noted above, however, General Mills strongly opposes FDA’s attempt to use this guidance document to impose the whole wheat bread standard of identity on other whole grain products, as proposed for “whole wheat bagel” or “whole wheat pizza.” If FDA intends to introduce new standards of identity, FDA must pursue rulemaking to do so. This draft guidance is not the appropriate forum for such an action.

Question 10: What types of label statements about whole grains are currently permitted to be made on food products?
As noted above, General Mills agrees that truthful and nonmisleading statements of whole grain content should be encouraged on food labels. We do not agree, however, that mere factual statements of gram or percentage amounts of whole grain are inherently nonmisleading. In some cases, such a statement should be accompanied by contextual information about recommended intake to provide meaningful information to a consumer. General Mills also disagrees with FDA’s citation to 21 CFR 101.13(i)(3) as authority to discourage statements that may imply particular levels of the whole grain ingredient in a food. That section only applies to statements about nutrients, and therefore is irrelevant to statements that may imply a particular level of whole grain.

Such statements may be made in a truthful and nonmisleading way, by providing contextual information to the consumer. It is inappropriate for FDA to categorically discourage the use of these terms. General Mills believes that FDA should rather encourage the use of these terms in a truthful and nonmisleading fashion, as noted above, to assist the consumer in identifying foods that will help them meet the recommendation of the Dietary Guidelines for whole grain intake.

General Mills proposes that FDA include the use of terms such as "good source" and "excellent source" in its list of terms to encourage. Those terms should only be used on foods that provide significant amounts of whole grain (at least 8 grams and 16 grams, respectively, per labeled serving), and should be accompanied by quantitative statements of whole grain content, as well as a statement of the minimum daily recommended amount of whole grain (at least 48g daily).

Question 11: Can the name of the particular whole grain be substituted for the term "whole grain" in label statements? For example, could the statement "100% brown rice" replace the statement "100% whole grains" or "1 ounce whole wheat" replace "1 ounce whole grain?"

We agree with FDA's guidance that specific names for whole grains can be used rather than the more general term, "whole grain."

Conclusion

As noted above, General Mills supports FDA's efforts to define the terms whole grain to provide for uniformity in the use of the term. General Mills also supports the use of truthful and nonmisleading statements on food labels to describe the whole grain content of a food. General mills does not agree that factual statements alone will always achieve this, however, and therefore these statements should be made in the context of the overall daily recommendation for whole grain intake. Also, statements that may imply a particular level of whole grain can be made in a truthful and nonmisleading manner, and the use of these terms should be encouraged. Increased consumption of whole grains is recommended by health professionals and government experts. FDA has an excellent opportunity to facilitate consumer understanding of what foods provide meaningful amounts of whole grain thereby helping consumers meet Dietary Guidelines recommendations for whole grain intake. General Mills encourages FDA to embrace this opportunity, and encourage the use of truthful and nonmisleading label statements that will assist consumers in their efforts to increase whole grain intake.

Respectfully submitted,

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Appendix 1

Support for 48g as Minimum Daily Whole Grain Intake

While there is no "Daily Value" for whole grains, both MyPyramid and the Dietary Guidelines recommend that consumers eat at least 3 "ounce-equivalents" (which equates to at least 48 grams) of whole grain a day (for a 2000 calorie diet). The amount of whole grain necessary in a food to qualify for a descriptive claim should be based upon these recommendations. In other words, FDA should use the MyPyramid "3 ounce-equivalents" as the functional equivalent of a recommended daily amount of whole grain. This provides the necessary benchmark for deciding how much whole grain is a meaningful amount.

In epidemiological studies examining whole grain intake, whole grain foods were classified in food frequency questionnaires based on the methods of Jacobs et al (1998) and Liu et al (1999). Whole-grain items included brown rice, dark breads , whole-grain ready-to-eat cereals, cooked cereal, popcorn, wheat germ, bran, and other grains. Classification of whole-grain ready-to-eat cereals was based on having 25% whole-grain or bran content by weight. (Refined-grain foods included white bread, white rice, English muffins, pancakes, waffles, cakes, sweet rolls, refined-grain ready-to-eat cereals, muffins and biscuits, and pizza.)

The majority of studies classified quintiles of whole grain intake by servings. These showed that the median intake ranged from 0.4 servings/d at the lowest quintile to 2.7 to 3.2 servings/d at the highest quintiles. Koh-Banerjee (2004) and Jensen (2004; 2006) calculated median whole grain intakes in grams per day as 3.0g to 8.8g for the lowest quintile and 42.7g to 43.8 g for the highest quintile. Jensen (2004) also reported a mean range of whole grain intake of 3.3g/d to 49.6 g/d for the lowest and highest quintiles.

Available studies show that risk reduction associated with consuming whole grain ranges from as little as 1 serving daily up to 3 servings per day. Comparatively, Koh-Banerjee and Jensen quantified whole grain intake and observed a benefit from a range of 42.7 to 43.8 g/d based on median intake, and 49.6 g/d based on mean intakes. Comparing the analyses of whole grain consumption only from products that would qualify for the FDA Whole Grain Health Claim (≥51% whole grain by weight) to the analyses of whole grain from all foods did not change the associated benefits. This suggests the health benefits of whole grain are independent of the whole grain concentration of the food source (Jensen et al, 2004) when total intake of whole grain is comparable.

Current dietary guidance recommends the consumption of at least 3 servings (or ounce-equivalents) of whole grain each day. Review of the scientific literature on the health benefits of whole grain also supports consumption of 3 servings per day, or a range of 42.7 to 43.8 g/d or 49.6g based on mean intakes. The most frequently consumed

grain-based food in the American diet is white bread (NHANES 99-02). Applying the rationale that the reference weight for a standard size slice of commercial bread (26 g) contains 16 g of grain (USDA Pyramid Servings Database), 3 servings of bread would provide 48 g of grain, or in essence 48 g of whole grain.

Thus, the foundation of using the standard reference 16 g of whole grain per serving – the amount of grain found in whole grain bread – seems most practical in the context of what is the most commonly consumed grain food in the diet, and a minimum goal of consuming 48 g per day is recommended for a variety of health benefits.

Summary and Recommendation to Define 48g/day as the Recommended Daily Intake

These data consistently indicate consuming the equivalent of 3 servings (median 42.7-43.8g or mean 49.6g) of whole grain per day is nutritionally significant to reduce chronic diseases in certain populations. Consuming a minimum of 48 g of whole grains per day will not only help consumers meet the Dietary Guidelines' recommendations, but will also provide important health-promoting dietary components including fiber, vitamins, minerals, and other phytonutrients. We recognize that, just as the Dietary Guidelines are re-examined every five years to apply new science, the daily intake recommended for whole grains may change in the future as more precise studies link specific quantities of whole grain consumption to specific health benefits.

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