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May 10, 2004

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

Dear Sir or Madam:

Enclosed are the Citizen Petition and attachments submitted by General Mills, Inc. In total, there are four (4) volumes that contain:

- |                       |            |
|-----------------------|------------|
| Citizen Petition      | Volume I   |
| Attachments 1-2       | Volume II  |
| Attachment 2 (cont'd) | Volume III |
| Attachments 3-20      | Volume IV  |

In addition to the enclosed attachments, there are proprietary studies that are cited in the petition but have not been included. These studies contain confidential commercial information that is privileged or confidential pursuant to 21 C.F.R. 20.61(b). However, GMI will provide these studies upon the Agency's request, subject to agreement on appropriate procedures to maintain the confidentiality of the proprietary studies.

If you have any questions or require additional information, please do not hesitate to contact us.

Sincerely,  
  
Stuart M. Pape  
Counsel to General Mills, Inc.

2004P-0223

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# **Whole Grain Descriptive Claims**

## **Citizen Petition**

**Submitted on behalf of  
General Mills, Inc.**

**By  
Stuart M. Pape  
Patton Boggs LLP  
2550 M Street, NW  
Washington, DC 20037**

**Volume I  
Citizen Petition**

**Citizen Petition**

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

The undersigned submits this petition, on behalf of General Mills, Inc. ("GMI"), under Sections 201(n), 403(a)(1) and 701(a) of the Federal Food Drug and Cosmetic Act ("FD&C Act")<sup>1</sup> and Section 10.30 of the Food and Drug Administration's ("FDA's") procedural regulations.<sup>2</sup> The undersigned requests the FDA to establish the descriptive claims "excellent source," "good source," and "made with" for whole grain content under the Agency's authority to prevent false and misleading food labeling statements.

**I. Action Requested**

GMI requests that the FDA establish definitions for "excellent source," "good source," and "made with" as descriptors for whole grain content under the Agency's authority in the FD&C Act to prevent false and misleading food labeling statements.<sup>3</sup> GMI further requests that FDA establish these claims using a two-step approach by first, establishing a guidance document and exercising its enforcement discretion when evaluating the appropriate use of the claims and, subsequently, initiating rulemaking to formalize the descriptors "excellent source," "good source," and "made with" for whole grain content as proposed in Attachment 1.

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<sup>1</sup> 21 U.S.C. §§ 321(n), 343(a)(1), and 371(a).

<sup>2</sup> 21 C.F.R. § 10.30.

<sup>3</sup> GMI recognizes that it may be argued that FDA may also establish such descriptors for whole grain under its authority to regulate nutrient content claims. Since the substance "whole grain" is not a nutrient, but rather a beneficial ingredient for which claims should be defined, the Agency should regulate whole grain claims as descriptive claims that are neither nutrient content nor health claims. This is also consistent with consumers' general understanding of whole grain as a substance in food.

## II. Statement of Grounds

### A. Introduction

FDA created the Consumer Health Information for Better Nutrition ("CHIBN") Initiative to assist consumers in making wise dietary choices by providing more and better information about conventional foods and dietary supplements that will help prevent disease and improve health. The CHIBN Task Force was formed and published a final report that provided the Agency with recommendations.<sup>4</sup> Among its recommendations, the CHIBN Task Force emphasized the need to improve consumers' understanding of health consequences from their dietary choices.

To formalize the CHIBN Task Force recommendations, FDA published in the *Federal Register* of November 25, 2003, an Advanced Notice of Proposed Rulemaking for food labeling, health claims, and dietary guidance (hereinafter referred to as the "ANPR"), which requested, among other things, comments on whether whole grains qualified as a substance or broad category of food.<sup>5</sup> Clearly, whole grains are a substance. However, the critical public health issue is how consumers can best be encouraged to incorporate this valuable substance into their diet.

Scientific evidence shows that significant health benefits exist from regular consumption of whole grains, and these benefits are attributed to the entire nutrient profile of whole grain (not limited to merely its fiber content).<sup>6</sup> FDA has permitted the use of health claims relating whole grain consumption with reduced risk of heart disease and certain cancers.<sup>7</sup> In addition, emerging science has indicated that whole grains may also have a beneficial effect on weight management and diabetes among other chronic diseases.

Consumers are receptive to messages about nutrition and health and are interested in learning more about these foods.<sup>8</sup> Studies also show that

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<sup>4</sup> FDA, Center for Food Safety and Applied Nutrition, Consumer Health Information for Better Nutrition Initiative: Task Force Final Report, July 10, 2003.

<sup>5</sup> 68 Fed. Reg. 66040 (Nov. 25, 2003).

<sup>6</sup> The scientific publications cited in this petition are included at Attachment 2.

<sup>7</sup> 21 C.F.R. §§ 101.76 and 101.77, Docket No. 99P-2209, and Docket No. 03Q-0547.

<sup>8</sup> IFIC 2002 IFIC, Functional Foods: Attitudinal Research (2002), available at [www.ific.org/research/FuncFoods res.02.cfm](http://www.ific.org/research/FuncFoods res.02.cfm). (Attachment 3)

consumers believe that whole grains contain important nutritional qualities.<sup>9</sup> Nonetheless, studies have consistently demonstrated that consumption of whole grains is only a fraction of the daily intake recommended by the Department of Health and Human Services ("DHHS")/United States Department of Agriculture ("USDA") Dietary Guidelines for Americans<sup>10</sup> ("Dietary Guidelines") and USDA Food Guide Pyramid.<sup>11</sup> These studies have also identified factors that have contributed to lower than recommended consumption levels of whole grain, which are: (1) consumers' low awareness of the health benefits of whole grain; (2) the absence of clear, consistent labeling to identify whole grain foods; and (3) the unpalatable taste of some food products with high levels of whole grain.<sup>12</sup>

In light of the CHIBN and other consumer health programs initiated by FDA, the issue of whole grain is not limited to merely clarifying its classification as a substance. Rather, FDA should also address a greater public health need of assisting consumers in increasing their whole grain consumption. This may be achieved, in part, by providing consumers with a readily accessible means of

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<sup>9</sup> Data are derived from The 2001 Gallup Study of Attitudes Towards and Knowledge of Cholesterol and Saturated Fats and General Mills Proprietary Study #1. The relevant section of the Gallup study has been provided at Attachment 4. Because the Gallup and other third party studies cited in this petition are considered proprietary, GMI is not permitted to release the entire study. The proprietary GMI studies cited in this petition were conducted for purposes other than the whole grain descriptors proposed herein. Although the methodologies employed in these studies reflect a different purpose, the data provide useful information that may assist the Agency in developing the proposed whole grain descriptors. Additionally, because the consumer survey studies contain commercial information that is privileged or confidential pursuant to 21 C.F.R. 20.61(b), the information is not included in these comments, but will be provided to the FDA upon request.

<sup>10</sup> U.S. Department of Agriculture, U.S. Department of Health and Human Services, Nutrition and Your Health: Dietary Guidelines for Americans, 2000. (Attachment 5)

<sup>11</sup> Welsh, S., et al., Achieving Dietary Recommendations: Whole-Grain Foods in the Food Guide Pyramid, *Critical Reviews in Food Science and Nutrition*, 34(5&6):441-451 (1994); Schwartz, N., Narrowing the Gap: Practical Strategies for Increasing Whole-Grain Consumption, *Critical Reviews in Food Science and Nutrition*, 34(5&6):513-516 (1994); Adams, J., Helping Consumers Achieve Recommended Intakes of Whole Grain Foods, *Journal of American College of Nutrition*, 19(3):339S-344S (2000); Kantor, L., Choose a Variety of Grains Daily, Especially Whole Grains: A Challenge for Consumers, *Journal of Nutrition*, 131:473S-486S (2001); and Jones, J., The Importance of Promoting a Whole Grain Foods Message, *Journal of the American College of Nutrition*, 21(4):293-297 (2002).

<sup>12</sup> Kantor, L., et al., The Dietary Guidelines: Surveillance Issues and Research Needs, Choose a Variety of Grains Especially Whole Grains: A Challenge for Consumers, *Journal of Nutrition*, 131:473-486S (2001); and Adams, J., et al., Helping Consumers Achieve Recommended Intakes of Whole Grain Foods, *Journal of American College of Nutrition*, 19(3):339S-344S (2000).

identifying food products with dietarily significant levels of whole grain through food labels. Specifically, GMI proposes that FDA establish the following descriptors for whole grain:

- Excellent Source of Whole Grain: 16 grams (g) or more per labeled serving;
- Good Source of Whole Grain: 8-15 g per labeled serving; and
- Made with Whole Grain: at least 8 g per labeled serving.

Studies show that there is strong support for these proposed whole grain descriptors. Consumers have responded positively to these claims, which may increase whole grain consumption and result in better health and nutrition.

Under Sections 201(n), 403(a)(1), and 701(a) of the FD&C Act, FDA may establish the proposed whole grain claims as descriptors that are neither nutrient content claims nor health claims. This action is consistent with the Agency's precedent regarding other descriptive food labeling claims such as "fresh." During the implementation of the Nutrition Labeling and Education Act of 1990 ("NLEA"),<sup>13</sup> FDA determined that it was necessary to establish a definition for the uses of "fresh" and that the claim does not appropriately fall into the category of nutrient content or health claims.<sup>14</sup> The FDA also explained in the 1993 final rule that a definition for fresh and its related terms is necessary because of the consumer confusion that has resulted from its misuse and "that a regulatory definition will discourage such misuse and will allow the Agency to efficiently enforce the misbranding provisions of the Act, particularly Section 403(a), when the term is misused."<sup>15</sup> Likewise, the same rationale may be applied to the proposed whole grain descriptors; the lack of a definition for these claims may undermine the potential benefits that consumers may receive from increased whole grain consumption.

To establish the whole grain descriptors, the Agency should proceed in two-steps: first, issue a guidance document to encourage immediately the use of the descriptors in an appropriate way; and, second initiate rulemaking to formalize the claims. The proposed claims that may be used to develop the guidance and promulgate regulations are set forth in Attachment 1.

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<sup>13</sup> Pub. L. 101-535, 104 Stat. 2353 (1990).

<sup>14</sup> 21 C.F.R. 101.95; 58 Fed. Reg. 2302, 2401-2407 (January 6, 1993).

<sup>15</sup> 58 Fed. Reg. 2302 at 2402 (Jan. 6, 1993).

Implementing the claims through the two-step approach would allow consumers to access immediately the health and nutrition information relating to dietarily significant amounts of whole grains, while ensuring compliance through the use of the Agency's enforcement discretion followed by rulemaking. Adoption of the whole grain claims will encourage consumption of whole grain foods, eliminate consumer confusion about whole grain products and provide an incentive for manufacturers to increase the whole grain content of their products and, thus, provide a substantial benefit to public health. With the publication of updated Dietary Guidelines in January 2005, there will be increased attention to whole grains. By issuing guidance now, FDA will provide needed structure for manufacturers and consumers and avoid the likelihood of confusing label claims about the whole grain content of products, which will have heightened importance given the publicity attendant to the issuance of the Dietary Guidelines.

## **B. CHIBN Initiative**

On December 18, 2002, FDA announced the CHIBN Initiative to make available more and better information about foods and dietary supplements. Among its goals, the CHIBN Initiative is intended to help American consumers improve their health and prevent disease by making sound dietary decisions.

FDA specifically stated that its "mission at FDA is to improve health outcomes for the nation, and some of the best opportunities for improving health involve informed choices by consumers."<sup>16</sup> Through the CHIBN, FDA is "committed to improving opportunities for consumers to get scientifically accurate information about the health consequences of the foods they consume, and to enhancing our enforcement efforts against those who would make false or misleading claims for their products."<sup>17</sup> From this Initiative, the CHIBN Task Force, which was comprised of members of FDA, the Federal Trade Commission ("FTC") and the National Institutes of Health ("NIH") published its final report on July 10, 2003.<sup>18</sup>

In its report, the CHIBN Task Force emphasized the need to improve consumers' understanding of health consequences from their dietary choices. To assist consumers, the Task Force concluded that it is necessary for consumers to have access to and use more and better information to aid them in their food

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<sup>16</sup> Announcement of the CHIBN Initiative, December 18, 2002.

<sup>17</sup> *Id.*

<sup>18</sup> FDA, Center for Food Safety and Applied Nutrition, Consumer Health Information for Better Nutrition Initiative: Task Force Final Report, July 10, 2003.

purchases. Information should go beyond price, convenience, and taste by including science-based health factors. Consumers who are equipped with scientifically based information about the likely health benefits of foods may make a difference in their own long-term health by lowering their risk of certain chronic diseases.

### **C. ANPR for Food Labeling**

Based on the CHIBN Initiative, FDA published the ANPR to solicit comments on the possible approaches for regulating qualified health claims.<sup>19</sup> FDA requested, among other things, that interested parties provide comments on whether a specific authorized health claim about whole grain foods properly refers to a substance as compared to a broad category of foods. The health claim is based on an authoritative statement that was submitted by GMI on March 10, 1999, which contained a prospective claim about the relationship of whole grain foods and reduced risk of heart disease and certain cancers.<sup>20</sup> As discussed in the following sections, whole grains are properly categorized as a substance.

#### **1. What are Whole Grains?**

Whole grain includes all edible parts of the whole grain: the bran, germ and endosperm.<sup>21</sup> The American Association of Cereal Chemists ("AACC"), which is a non-profit international organization comprised of nearly 4,000 members who are specialists in the use of cereal grains in foods, has developed a definition of whole grain. The authoritative AACC definition is: "Whole grains shall consist of the intact, ground, cracked or flaked caryopsis, whose principal anatomical components – the starchy endosperm, germ and bran – are present in the same relative proportions as they exist in the intact caryopsis."<sup>22</sup>

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<sup>19</sup> 68 Fed. Reg. 66040 (Nov. 25, 2003).

<sup>20</sup> Docket No. 99P-2209.

<sup>21</sup> See e.g., USDA, Get on the Grain Train, May 2002; and American Dietetic Association, and Whole Grain for Healthful Eating, 2000. (Attachments 6 and 7, respectively)

<sup>22</sup> AACC definition of whole grains available at: <http://www.aaccnet.org/definitions/wholegrain.asp>. (Attachment 8)

Food ingredients that are considered whole grain have been classified by USDA and include, among others, barley, buckwheat, corn, oats, rice, and wheat.<sup>23</sup> In preparation for human consumption, grains are typically subjected to processing. Processed foods are considered to contain whole grain if all three components (i.e., bran, germ, and endosperm) of the grain are present in the same proportions as found in nature. Whole grains are an important source of dietary fiber, resistant starch, vitamins and minerals.<sup>24</sup>

In addition, whole grains naturally contain bioactive compounds or phytonutrients believed to play a role in protection against chronic disease. Such substances include various antioxidants, phytoestrogens and oligosaccharides. Research has shown that the antioxidant content of whole grains, including whole grain breakfast cereals, is higher than most common fruits and vegetables.<sup>25</sup> These antioxidant compounds are capable of preventing or minimizing oxidative damage, which may contribute to decreased risk of cancer and coronary heart disease. The health benefits of whole grains are considered to be due to synergy among traditional nutrients and other components.<sup>26</sup>

Whole grain is or can be a dietarily significant component of a broad category of foods including: breads, cereals (ready-to-eat and hot), crackers, grain snacks and bars, pasta, rice dishes, grain side dishes, and main meals and dinners. The many different types of food that can incorporate significant

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<sup>23</sup> Food Ingredients Classified as Whole Grain in USDA's Pyramid Servings Database include an extensive list of grains that may be considered whole grains. See, Cleveland, L.E. et al., Dietary intake of whole grains, *Journal of American College of Nutrition*, 19(3):331S-338S (2000).

<sup>24</sup> USDA analysis of the nutrient content of whole grains commonly found in the American diet. See, USDA National Nutrient Database for Standard Reference available at [http://www.nal.usda.gov/fnic/foodcomp/cgi-bin/list\\_nut\\_edit.pl](http://www.nal.usda.gov/fnic/foodcomp/cgi-bin/list_nut_edit.pl).

<sup>25</sup> Miller, H.E., et al., Antioxidant content of whole grain breakfast cereals, fruit and vegetables, *Journal of the American College of Nutrition*, 19(3):312S-319S (2000).

<sup>26</sup> Slavin, J., et al, Why whole grains are protective: biological mechanisms, *Proceedings of the Nutrition Society*, 62, 129-134 (2003); Jacobs, D.R., et al., Nutrients foods, and dietary patterns as exposures in research: a framework for food synergy, *American Journal of Clinical Nutrition*, 78 (suppl):508S-13S (2003); Adom, K.K., et al., Antioxidant Activity of Grains, *Journal of Agricultural Food Chemistry*, 50:6182-6187 (2002); Miller, H.E., et al., Antioxidant content of whole grain breakfast cereals, fruit and vegetables, *Journal of the American College of Nutrition*, 19(3):312S-319S (2000); and Baublis, A.J., et al., Potential of wheat-based cereals as a source of dietary antioxidants, *Journal of the American College of Nutrition*, 19(3):308S-311S (2000); and Slavin, J., et al., Plausible mechanisms for the protectiveness of whole grains, *American Journal of Clinical Nutrition*, 70(suppl):459S-63S (1999).

quantities of whole grain provide an excellent opportunity to increase whole grain consumption that is consistent with public health recommendations.

## **2. Whole Grain is a Substance Not a Broad Category of Food**

In the ANPR, FDA specifically requested comments on the categorization (i.e., substance versus broad category of food) of whole grains.<sup>27</sup> Under the regulations, a "substance" is defined as "a specific food or component of a food regardless of whether the food is in conventional form or a dietary supplement of vitamins, minerals, herbs or other nutritional substances."<sup>28</sup> It is clear that whole grain falls squarely in the definition of substance.

Whole grain is the primary component of many different types of foods, such as breakfast cereals, breads, pastas, side dishes, crackers, and other bakery items. It is also used as a descriptor of these products, which signals consumers to the products' ingredients. The Dietary Guidelines also encourage consumers to seek out whole grain foods by referring to the ingredient list on the food label. Consumers have focused on whole grain as a component rather than a broad category of food. This is further demonstrated by a typical grocery store where consumers do not search for a whole grain aisle but naturally find whole grains within various food product categories.

It would be contrary to the established definition of "substance" and consumers' general understanding to categorize whole grains as a broad category of food products. Therefore, whole grains are properly classified as a substance.

## **D. Based on FDA's Current Consumer Health Initiatives a Critical Public Health Issue is Increasing Consumption of Whole Grain**

In addition to the CHIBN Initiative, FDA recently created the Obesity Working Group ("OWG"), which proposed an action plan, "Calories Count," to confront the nation's rising obesity epidemic. Adult obesity has steadily and substantially increased in the United States. Almost two-thirds of all Americans are overweight or obese. A similar alarming pattern is seen in children. Numerous health problems originate with increased weight gain and strain the economy with avoidable medical costs that exceed \$50 billion each year. The CHIBN Initiative and OWG maintain similar goals and, in fact, work in concert with each other. By providing consumers with increased information about good nutrition

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<sup>27</sup> 68 Fed. Reg. at 66047.

<sup>28</sup> 21 C.F.R. § 101.14(a)(2).

and health benefits, consumers are better equipped to combat chronic disease and obesity.

In light of these consumer health initiatives, the issue of whole grains goes well beyond its classification as a substance. Studies show that, although numerous health benefits including weight management are associated with regular consumption of whole grains, consumers fail to consume the DHHS/USDA recommended servings. GMI, through its effort in obtaining an authoritative statement about whole grains and certain cancers and heart disease, has elevated consumers' awareness about the health benefits of whole grain. However, FDA must take the next step and facilitate consumption of whole grains by providing a meaningful mechanism for consumers to readily identify food products that contain dietarily significant levels of whole grains. As set forth in this petition, the proposed descriptors for whole grain and two-step implementation process provide consumers with a useful tool to begin meeting the recommended daily servings of whole grains and obtain the associated health benefits.

## **E. DHHS/USDA Recommendation for Whole Grains in its Dietary Guidelines and Food Guide Pyramid**

### **1. Background on Dietary Guidelines**

The Dietary Guidelines have evolved over time to reflect the changing science about certain nutrients and other components of food and to educate consumers regarding this information. Over time, the Guidelines have increased emphasis on whole grain consumption, as science has broadened our understanding of the benefits associated with this substance.

Initially, in the 1980's, the Guidelines consisted of "Eat Foods with Adequate Starch and Fiber." However, emerging science demonstrated that there are different types of fiber playing a key role in health. With that knowledge, the message in the 1990 Guidelines was revised to "Choose a Diet with Plenty of Vegetables, Fruits and Grain." The 1990 Dietary Guidelines were the first to quantify the minimum number of servings of grains and other foods, which included 6-11 servings of grain daily. In 1992, the Food Guide Pyramid was published to provide a graphic representation of the Dietary Guidelines. The Guideline statement was reworded in 1995 to "Choose a Diet with Plenty of Grain Products, Vegetables and Fruits" properly reflecting the position of grain products at the base of the Food Guide Pyramid, and their role as the largest source of energy in the diet.

The Food Guide Pyramid for Young Children 2 to 6 Years Old was released by USDA in 1999. The purpose of this educational tool is to communicate the same

general messages as the adult Food Guide Pyramid by using foods and serving sizes more appropriate for young children. Whole grains are prominently pictured on the Pyramid graphic, and accompanied by text including the following recommendation, "Offer whole or mixed grain products for at least three of the six grain group choices the Pyramid recommends each day."

## **2. 2000 Dietary Guidelines and Food Guide Pyramid**

In 2000, the guideline statement was reworded to "Choose a Variety of Grains Daily, Especially Whole Grains" to emphasize the importance of consuming whole grain foods. The modifications to the 2000 Dietary guidelines differ from the previous statements by: (1) establishing a guideline for grain products that is separate from fruits and vegetables, (2) placing a new emphasis on a variety of grain consumption, and (3) specifically recommending whole grains. The Advisory Committee for the 2000 Dietary Guidelines stated that new scientific evidence showed unique health benefits of whole grains, *and these benefits are related to factors distinct from its fiber content*. The Dietary Guidelines currently suggest 6-11 servings of grain products. Although no exact number of whole grain servings is specified, the Dietary Guidelines recommend several servings of whole grain. Many organizations, including the American Dietetic Association, have identified 3 whole grain servings as a minimum number that should be consumed daily.<sup>29</sup>

The Food Guide Pyramid is currently undergoing an evaluation process that is separate from the Dietary Guidelines. USDA's technical assessment of the Pyramid continues to recommend 6-11 servings of grain products with the additional recommendation that at least half of the servings come from whole grains. With the proposed definitions, if consumers choose good sources of whole grain for their grain servings, they will also satisfy this recommendation. Comments that were received from health professional organizations, health experts, and consumers consistently and overwhelmingly supported the whole grain recommendation.

## **3. 2005 Dietary Guidelines**

The 2005 Dietary Guidelines are in the process of being revised. The Dietary Guidelines Advisory Committee formed a Carbohydrates Subcommittee to evaluate the role of whole grains (independent of fiber). Information was

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<sup>29</sup> See, Welsh, S., et al., Achieving dietary recommendations: whole grain foods in the food guide pyramid, *Critical Reviews in Science and Nutrition*, 34:441-451 (1994); and American Dietetic Association, *Get the Whole Grain Picture*, available at: [http://www.eatright.org/print/index\\_18475.cfm](http://www.eatright.org/print/index_18475.cfm) (Attachment 9).

presented to the Committee that included recent findings about the health benefits of whole grain. Dr. Joanne Slavin of the University of Minnesota presented data and testified that the benefits of whole grain are not limited to its fiber content, as whole grains also provide antioxidants, phytoestrogens, oligosaccharides, vitamins, minerals, and resistant starch. Also, Dr. Slavin presented studies that showed whole grains contribute to weight loss as well as contain protective properties against cardiovascular disease, cancer, diabetes, and obesity.<sup>30</sup> In light of the favorable scientific evidence that points to the health benefits of the entire whole grain, it is most likely that whole grain will again be emphasized in the 2005 Dietary Guidelines along with a recommendation to increase consumption of whole grains. It is anticipated that the 2005 Dietary Guidelines will be published in January 2005.

As seen by the progression of the Dietary Guidelines, whole grains are recognized as an important and valuable food component in the daily diet. However, despite increased recognition of whole grains by DHHS/USDA, consumers still fail to consume adequate servings of whole grains daily. The proposed descriptor claims for whole grains provide a simple and straightforward means for consumers to use FDA's food label to meet the USDA/DHHS recommendations for whole grain intake. A consistent labeling standard will also make it easier for health professionals to guide consumers in their healthy food choices.

## **F. Health Benefits of Whole Grain**

### **1. Whole Grain Health Claims Authorized by FDA**

#### **a. Health Claim about Fiber Containing Fruit, Vegetable, and Grain Products and Heart Disease and Cancer – 21 CFR §§ 101.76 & 101.77**

During the implementation of NLEA, FDA evaluated certain health claims to determine whether adequate scientific evidence existed to justify promulgating regulations permitting its use. Among these claims, the health claims relating fiber-containing grain products (and fruit) to reduced heart disease and cancer were approved.<sup>31</sup>

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<sup>30</sup> See, Presentation of Dr. Joanne Slavin, University of Minnesota to the Dietary Guidelines Advisory Committee, January 28-29, 2004. (Attachment 10)

<sup>31</sup> 21 C.F.R. §§ 101.76 and 101.77.

As discussed in further detail in the following sections, scientific evidence continues to show that the health benefits of whole grain are attributed to the entire substance, not merely its fiber content. Whole grain has been associated with weight management and the reduced risk of heart disease, cancer, and diabetes mellitus, all of which have been identified by FDA as increasing public health concerns.

**b. Authoritative Statements about Whole Grain and Reduced Risk of Heart Disease and Certain Cancers**

On March 10, 1999, GMI submitted a notification for a health claim about the relationship of whole grain foods and heart disease and certain cancers.<sup>32</sup> The notification was based on the authoritative statements from the National Academy of Sciences ("NAS") in its report on *Diet and Health: Implications for Reducing Chronic Disease Risk*.<sup>33</sup> Along with the NAS cite, GMI also provided an extensive list of scientific articles that supported NAS's statement.

FDA recognized the value of whole grains and did not object to the notification submitted by GMI, which at the end of the requisite time period permitted the use of the claim. Through its efforts, GMI has increased consumers' awareness of the positive health benefits associated with whole grain consumption. Subsequently, FDA permitted the expansion of the whole grain health claim as a result of a notification submitted by Kraft in 2003. Recognition by the NAS as well as FDA's acknowledgement of attributes associated with whole grain demonstrates that whole grains play a critical role in the health of the U.S. population. The proposed claims "excellent source," "good source" and "made with" for whole grain supplement these health claims and further FDA's efforts to promote public health.

**2. Whole Grain Recommendations from Distinguished Health Organizations**

Countless other health organizations have recognized the scientific evidence correlating positive health benefits with the consumption of whole grains. The following are recommendations by these distinguished health organizations:

DHHS - Healthy People 2010: The purpose of the "Healthy People" publications is to define a national strategy for significantly improving the

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<sup>32</sup> Docket No. 99P-2209.

<sup>33</sup> Committee on Diet and Health, NAS, *Diet and Health: Implication for Reducing Chronic Disease Risk*, (1989). (Attachment 11)

health of the nation. The first publication, Healthy People 2000, did not specifically address whole grain intake, but included a broad objective to increase complex carbohydrate and fiber-containing foods, including 6 or more daily servings of grain products.

This objective was revised in Healthy People 2010. The *Healthy People Goals and Objectives for the Nation* established a goal of at least three daily whole grain servings for 50% of the US population by 2010.<sup>34</sup> The revised goal demonstrates a greater understanding of the relationship between whole grain consumption and public health as reflected in the 2000 Dietary Guidelines for Americans.

The American Cancer Society: Guidelines for the prevention and early detection of cancer from the American Cancer Society recommend that Americans "choose whole grains in preference to processed (refined) grains and sugars."<sup>35</sup>

The American Diabetes Association: The American Diabetes Association's most current recommendations for the treatment and prevention of diabetes emphasize the importance of whole grains in the diets of all Americans and include the following: "people with diabetes are encouraged to choose a variety of fiber-containing foods, such as whole grains, fruits and vegetables, because they provide vitamins, minerals, fiber, and other substances important for good health."<sup>36</sup>

The American Dietetic Association: The American Dietetic Association recently emphasized the importance of whole grain foods in its position statement on dietary fiber: "there is substantial scientific evidence suggesting that vegetables, fruits and whole grains reduce risk of chronic diseases, including cancer and heart disease...Additionally, recent studies suggest that whole grain foods offer more protection against chronic diseases than dietary fiber, antioxidants, or other biologically active components in foods."<sup>37</sup>

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<sup>34</sup> DHHS, Healthy People 2010: Understanding and Improving Health, Objective 19-7 (2000).

<sup>35</sup> American Cancer Society, *The Complete Guide – Nutrition and Physical Activity*, 2002. (Attachment 12)

<sup>36</sup> American Diabetic Association, *Eating Healthy*, 2004. (Attachment 13)

<sup>37</sup> American Dietetic Association, *Whole Grains for Healthful Eating Recipe*, 2000. (Attachment 7)

The American Heart Association: Revised dietary guidelines from the American Heart Association specifically suggest frequent consumption of whole grain foods with the following recommendation: “consume a variety of grain products, including whole grains; choose 6 or more servings a day. Grain Products provide complex carbohydrates, vitamins, minerals, and fiber. Dietary patterns high in grain products and fiber have been associated with decreased risk of cardiovascular disease.”<sup>38</sup>

### **3. Scientific Evidence Related to the Health Benefits of Whole Grain**

#### **a. Whole Grain and Cardiovascular Disease**

Cardiovascular disease (“CVD”) is the leading cause of death of both men and women in the United States. There exists strong epidemiological and clinical evidence linking consumption of whole grains to a reduced risk of CVD. This is illustrated by the current whole grain health claim that was allowed by the FDA in 1999. Since that time, additional lines of evidence have been published that further support a beneficial relationship between whole grain foods and heart health. A recent meta-analysis revealed that 7 of 8 epidemiological studies assessing whole grain intake and risk of CVD reported a negative association, with 6 reporting a significant negative association.<sup>39</sup> The relative risk ratio for whole grains comparing the lowest and highest groups of whole grain intake was 0.71 (95% CI 0.48, 0.94), indicating that whole grains were associated with a significant reduction in risk of approximately 29%. The authors concluded that whole grain foods may have more protective action against CVD than other foods commonly consumed in the American diet.

A similar meta-analysis examined 147 original investigations in attempts to review metabolic, epidemiologic, and clinical investigations of major dietary factors and prevention of CVD.<sup>40</sup> The findings indicated that one of 3 dietary strategies effective in preventing CVD was to consume a diet high in fruits, vegetables and whole grains.

Evidence has also suggested that consumption of whole grain foods can favorably alter various risk factors for CVD including: elevated serum and low

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<sup>38</sup> Krauss, R. M., et al., AHA Dietary Guidelines, Revision 2000.

<sup>39</sup> Anderson, J.W., et al., Whole grain foods and heart disease risk, *Journal of the American College of Nutrition*, 19(3):291-299S (2000).

<sup>40</sup> Hu, F.B., et. al., Optimal diets for prevention of coronary heart disease, *Journal of American Medical Association*, 288:2569-2578 (2002).

density lipoprotein ("LDL") cholesterol, hypertriglyceridemia, insulin resistance, hyperhomocysteinemia, and hypertension.<sup>41</sup>

## **b. Whole Grain and Cancer**

There currently exists substantial scientific evidence suggesting that whole grain foods commonly consumed in the United States and Europe reduce the risk of certain cancers. This relationship is described as part of the current whole grain health claim. Recent population-based studies have also reported an inverse association between whole grain intakes and cancer risk. Case-control studies examining the relationship between food groups and incidence of colorectal cancer<sup>42</sup> and esophageal cancer<sup>43</sup> found significant inverse associations with whole grain intake. Similarly, in crude dietary analysis of the Seven Countries cohort study, an increased intake of whole grains was associated with a decreased risk of mortality from colorectal cancer.<sup>44</sup> Kasum et al. investigated the association between whole grain intake and risk of upper aerodigestive

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<sup>41</sup> Steffen, L.M., et al., Associations of whole-grain, refined-grain, and fruit and vegetable consumption with risks of all-cause mortality and incident coronary artery disease and ischemic stroke: the Atherosclerosis Risk in Communities (ARIC) Study, *American Journal of Clinical Nutrition* 78:383-90 (2003); Frank B. Hu, Plant-based foods and prevention of cardiovascular disease: an overview, *American Journal of Clinical Nutrition* 78(suppl):544S-51S (2003); Anderson, J.W., Whole grains protect against atherosclerotic cardiovascular disease, *Proceedings of the Nutrition Society* 62, 135-142 (2003); Mozaffarian, D., et al., MPH, Cereal, Fruit, and Vegetable Fiber Intake and the Risk of Cardiovascular Disease in Elderly Individuals, *Journal of the American Medical Association*, 289:1659-1666 (2003); Liu, S., Intake of Refined Carbohydrates and Whole Grain Foods in Relation to Risk of Type 2 Diabetes Mellitus and Coronary Heart Disease, *Journal of the American College of Nutrition*, 21 (4): 298-306 (2002); Truswell, A.S., Cereal grains and coronary heart disease, *European Journal of Clinical Nutrition* 56:1-14 (2002); Fung, T.T. et al., Dietary Patterns and the Risk of Coronary Heart Disease in Women, *Archives of Internal Medicine* 161:1857-1862 (2001); Jacques, P.F., et al., Are dietary patterns useful for understanding the role of diet in chronic disease? *American Journal of Clinical Nutrition* 73:1-2 (2001); Hu, F.B., et al., Prospective study of major dietary patterns and risk of coronary heart disease in men, *American Journal Clinical Nutrition* 72:912-21 (2000); Liu, S., Whole-grain consumption and risk of coronary heart disease: results from the Nurses' Health Study, *American Journal of Clinical Nutrition* 70:412-9 (1999); Anderson, J.W., et al., Whole grains and protection against coronary heart disease: what are the active components and mechanisms? *American Journal of Clinical Nutrition* 70:307-8 (1999);

<sup>42</sup> Levi, F., et al., Food groups and colorectal cancer risk, *British Journal of Cancer*, 78(7/8):1283-1287 (1999).

<sup>43</sup> Levi, F., et al., Refined and whole grain cereals and the risk of oral oesophageal and laryngeal cancer, *European Journal of Clinical Nutrition*, 54:487-489 (2000).

<sup>44</sup> Slavin, J.L., Mechanisms for impact of whole grain foods on cancer risk, *Journal of the American College of Nutrition*, 19(3):300S-307(S) (2000).

tract cancers in the Iowa Women's Health Study.<sup>45</sup> Tertiles of average whole grain intakes were 3.3, 9.2 and 21.5 servings per week, respectively. Women in the upper tertile of whole grain intakes were 0.53 times less likely to develop cancer in the upper aerodigestive tract compared to women in the lowest tertile (95% CI 0.37, 0.84).

Whole grain foods are proposed to decrease cancer risk by a variety of mechanisms. Whole grains are rich sources of fermentable carbohydrates, including dietary fiber, resistant starch and oligosaccharides, all of which contribute to gastrointestinal health.<sup>46</sup> Naturally occurring antioxidant compounds including vitamins, trace minerals, and phytic acids delay the onset or slow down the rate of oxidation of reactive substances. Phenolic acids, located in the bran layer of grains, are potentially anti-carcinogenic through their ability to induce Phase II detoxification enzymes. Phytoestrogens, such as lignans, are estrogenic compounds found in plants that possess structural similarity to endogenous estrogens thought to have chemoprotective benefits.

### **c. Whole Grain and Diabetes Mellitus**

A growing body of evidence indicates a positive role for whole grain intake in reducing risk for type 2 diabetes. Examination of the Nurses' Health Study revealed an inverse relationship of whole grain intake to risk of type 2 diabetes.<sup>47</sup> The risk of diabetes after 10 years of follow-up was reduced by 38% (95% CI 0.53, 0.71) among women who consumed the most whole grain foods (median intake 2.71 servings/day) compared to those with the lowest intake of whole grains (median intake 0.13 servings/day). Assessment of the effect of specific whole grain foods demonstrated a statistically significant inverse association for intake of whole grain breakfast cereals ( $\geq 1/d$  vs.  $< 1/d$ ;  $p < 0.001$ ) and risk for diabetes. Investigation of the Iowa Women's Health Study demonstrated a 21% decreased risk for type 2 diabetes for women who ate the most whole grains ( $> 17.5$  servings/week) compared to those who consumed the least ( $< 3$  servings/week) after adjustment for lifestyle factors.<sup>48</sup>

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<sup>45</sup> Kasum, C.M., et al., Dietary Risk Factors For Upper Aerodigestive Tract Cancers, *International Journal of Cancer*,: 99:267-272 (2002).

<sup>46</sup> Slavin, J.L., Mechanisms for the Impact of Whole Grain Foods on Cancer Risk, *Journal of the American College of Nutrition*, 19(3):300S-307S (2000).

<sup>47</sup> Liu, S., et al. ,A prospective study of whole grain intake and risk of type 2 diabetes mellitus in U.S. women, *American Journal Public Health* 90:1409-15 (2000).

<sup>48</sup> Meyer, K.A., et al. Carbohydrates, dietary fiber, and incident type 2 diabetes in older women, *American Journal of Clinical Nutrition*, 71:921-30 (2000).

Fung et al. reported a decreased risk for type 2 diabetes in the Health Professionals Follow-up Study cohort.<sup>49</sup> The relative risk for type 2 diabetes was 0.58 (95% CI 0.47, 0.70) comparing the highest quintile (median intake 3.2 servings/day) to the lowest quintile (median intake 0.2 servings/day) of whole grain consumption. Findings from the Finnish Mobile Clinic Examination Survey reported whole grain consumption was associated with a significant reduced risk of type 2 diabetes.<sup>50</sup> The relative risk between the highest (302 g/day) and lowest (79 g/day) quintiles of whole grain intake was 0.65 (95% CI 0.36, 1.18). Cereal fiber intake was also associated with reduced diabetes risk.

Insulin sensitivity, which is an assessment of insulin resistance, is a precursor to the development of type 2 diabetes. An increase in insulin sensitivity is seen as a positive result in decreasing risk of future diagnosis with type 2 diabetes. The Insulin Resistance Atherosclerosis Study investigated the relationship between whole grain intake and insulin sensitivity.<sup>51</sup> The whole grain variable used to assess intake was based on a food frequency questionnaire that included dark breads, high fiber bran or granola cereals, shredded wheat, and cooked cereals. On average, study participants consumed 0.8 servings/day of whole grain foods. Whole grain intake was positively correlated with insulin sensitivity, and increasing intakes of whole grains was significantly associated with lower fasting insulin concentration ( $p=0.048$ ). Steffen et al. also reported whole grain intakes were significantly associated with greater insulin sensitivity in adolescents, especially those with a BMI  $>25$ .<sup>52</sup> In a cross-over, randomized feeding study among hyperinsulinemic, overweight adult men and women, insulin sensitivity significantly increased during consumption of a diet rich in whole grain foods (6-10 servings/day) for 6 weeks, but not while subjects were consuming a refined grain diet for 6 weeks.<sup>53</sup>

Taken together, findings for these studies strongly suggest a preventive effect of whole grain intake in the development of, and risk for, type 2 diabetes.

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<sup>49</sup> Fung, T.T., et al., Whole-grain intake and the risk of type 2 diabetes: a prospective study in men, *American Journal of Clinical Nutrition*, 76:535-40 (2002).

<sup>50</sup> Montonen, J., et al., Whole-grain and fiber intake and the incidence of type 2 diabetes, *American Journal of Clinical Nutrition*, 77:622-9 (2003).

<sup>51</sup> Liese, A.D., et al., Whole-grain intake and insulin sensitivity: the Insulin Resistance Atherosclerosis Study, *American Journal of Clinical Nutrition*, 78:965-71 (2003).

<sup>52</sup> Steffen, L.M., et al., Whole Grain Intake is Associated with Lower Body Mass and Greater Insulin Sensitivity among Adolescents, *American Journal of Epidemiology*, 158:243-250 (2003).

<sup>53</sup> Pereira, M.A., et al., Effect of whole grains on insulin sensitivity in overweight hyperinsulinemic adults, *American Journal of Clinical Nutrition*, 75:848-55 (2002).

#### d. Whole Grain and Body Weight

According to recent estimates, nearly 100 million US adults are overweight or obese.<sup>54</sup> A body mass index (BMI) over 25 is associated with increased risk of hypertension, dyslipidemia, type 2 diabetes, heart disease and other chronic diseases. Recently reported studies offer insight into the potential role that whole grain foods may play in body weight regulation. It is hypothesized that due to its natural components, whole grains may influence hormonal factors involved in appetite regulation, satiety, and satiation. Examination of the USDA's Continuing Survey of Food Intake of Individuals ("CSFII") dietary intake dataset revealed an inverse relationship between whole grain intake ( $\geq 3$  servings/day) and BMI in adult women.<sup>55</sup> Additionally, the percent of females classified as overweight/obese was lowest for those consuming 3 or more servings of whole grains per day compared to those consuming none. A logistic regression model predicted a decline in percent overweight with increasing whole grain consumption ( $p < 0.0001$ ).

Liu et al. investigated the association between whole grain intake and weight gain over time in the Nurses' Health Study cohort.<sup>56</sup> Over a 12-year period, women who consistently ate more whole grains (1.62 servings/1000 kcal/d) had a lower body weight than those who ate fewer whole grains ( $p < 0.0001$ ). Furthermore, an increased intake of whole grains was associated with significantly less weight gain over the course of the follow-up period. The relationship between whole grain consumption and 8-year weight gain was investigated in the Health Professionals' Follow-up Study.<sup>57</sup> An increase in whole grain intake was inversely associated with long-term weight gain ( $p < 0.0001$ ). In fact, a 100g increase in whole grain intake (approximately 2-3 servings) was associated with a  $-1.42\text{kg}$  weight reduction over 8 years. Consumption of ready-to-eat cereals with  $\geq 25\%$  whole grain content by weight was also inversely related to weight gain ( $p = 0.05$ ).

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<sup>54</sup> Flegal, K.M., et al., Prevalence and Trends in Obesity Among U.S. Adults, 1999-2000, *Journal of the American Medical Association*, 288; 1723-27 (2002).

<sup>55</sup> Albertson, A.M., et al., The Relationship Between Whole Grain Consumption and Body Mass Index in Adult Women, (abstract), *Journal of the American College of Nutrition*, 2003; 22:468

<sup>56</sup> Liu, S., et al., Relation between changes in intakes of dietary fiber and grain products and changes in weight and development of obesity among middle-aged women, *American Journal of Clinical Nutrition*, 78:920-7 (2003).

<sup>57</sup> Koh-Banerjee, P., et al., Changes in Whole Grain, Bran, and Cereal Fiber Consumption with 8-year Weight Gain among U.S. male Health Professionals Using New Quantitative Estimates of Whole Grain Intakes, Program Abstract, North American Association for the Study of Obesity, Annual Meeting 2003.

The Framingham Offspring Study reported a significant inverse association between whole grain intake (20.5 servings/week) and waist circumference.<sup>58</sup> Newby et al. evaluated the Baltimore Longitudinal Study on Aging for changes in BMI and waist circumference by dietary intake pattern.<sup>59</sup> Their findings indicated that a diet high in fruits, vegetables, reduced-fat dairy and whole grains and low in red and processed meat, fast food and soda was associated with significantly smaller gains in BMI and waist circumference over a 7-year period ( $p < 0.01$ ). In totality, this evidence suggests increased intakes of whole grain foods in the population may play a role in maintaining a healthy body weight, and preventing future weight gain.

#### **G. Despite Overwhelming Evidence that Whole Grains are Good for You, Consumption is Significantly Below Daily Recommended Levels**

Since FDA approved the first health claims about grain products during the implementation of NLEA, the scientific knowledge base about whole grains has grown substantially. Scientific evidence has revealed that there are significant health benefits associated with the entire whole grain. Whole grains are associated with decreased risk of cardiovascular disease, cancer, diabetes mellitus, as well as weight management.

Despite the abundance of information about the positive health effects of whole grains, and the increased emphasis on whole grains in dietary recommendations among Federal agencies and distinguished health organizations, consumers fail to consume the recommended 3 servings of whole grains daily. Indeed, the intake of whole grain products remains well below current dietary recommendations.<sup>60</sup> An analysis of the CFSII data discovered that only 8% of this group met the current recommendation to eat at least three servings per day.<sup>61</sup> Only 19% of Americans adults include 1 or more servings of whole grain foods in their diet each day. On average, adults consume 1.0

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<sup>58</sup> McKeown, N.M., et al., Whole-grain intake is favorably associated with metabolic risk factors for type 2 diabetes and cardiovascular disease in the Framingham Offspring Study, *American Journal of Clinical Nutrition* 76:390-8 (2002).

<sup>59</sup> Newby, P.K., et al., Dietary patterns and changes in body mass index and waist circumference in adults, *American Journal of Clinical Nutrition*, 77:1417-25 (2003).

<sup>60</sup> Jones, J.M., et al., The importance of promoting a whole grain foods message, *Journal of the American College of Nutrition*, 21(4):293-297 (2002).

<sup>61</sup> Cleveland, L.E., et.al., Dietary intake of whole grains, *Journal of the American College of Nutrition*, 19(3):331-3338S (2000).

serving of whole grain per day.<sup>62</sup> Similar results regarding average whole grain consumption were found for adolescents 2-18 years, whereas preschool aged-children reportedly consumed an average of only 0.8 servings of whole grain per day.<sup>63</sup> As demonstrated by the food consumption surveys, Americans eat far less than the currently recommended 3 servings of whole grains per day.

Whole grain consumption also differs by demographic group. Kantor et al. reported that the mean number of servings of whole grains eaten per day tends to be higher among U.S. Caucasians (1.1 servings/day) compared to non-Native American minorities (0.7 servings/day).<sup>64</sup> In addition, whole grain intake was associated with education level (1.2 servings/day for people with post-high school education vs. 0.8 for those who did not finish high school) and household income (0.8 vs. 1.2 servings/day for people with incomes <130% of the poverty level compared to those with >350% respectively). Cleveland et. al. found that health conscious consumers (e.g. exercisers, non-smokers, vitamin and/or mineral supplement users and non-overweight individuals) tended to eat more servings of whole grains than their less health conscious counterparts.<sup>65</sup> Clearly, these studies demonstrate that a significant percentage of Americans are not consuming nearly enough whole grains and are significantly below the recommended daily servings.

#### **H. Whole Grains Are Important to Consumers**

Although consumption of whole grains is below recommended levels, consumers believe whole grains are important. Consumers place importance on natural and complete nutrition and ranked whole grains as 11<sup>th</sup> in importance among items of nutrition, and 51% of consumers state that it is important for their cereal to contain whole grains.<sup>66</sup> The majority of consumers

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<sup>62</sup> *Id.*

<sup>63</sup> Harnack, L. et al., Dietary Intake and Food Sources of Whole Grains Among U.S. Children and Adolescents: Data from the 1994-1996 Continuing Survey of Food Intakes by Individuals, *Journal of American Dietetic Association*, 103: 1015-19 (2003).

<sup>64</sup> Kantor, L.S., et al, The Dietary Guidelines: Surveillance Issues and Research Needs, Choose a Variety of Grains Daily Especially Whole Grains: A Challenge for Consumers, *Journal of Nutrition* 131: 473S-486S (2001).

<sup>65</sup> Cleveland, L.E., et al., Dietary Intake of Whole Grains, *Journal of the American College of Nutrition*, Vol. 19, No. 3, 331S-338S (2000).

<sup>66</sup> GMI Proprietary Study #1.

also understand that whole grains are generally good for them,<sup>67</sup> and 66% of consumers are receptive to whole grain claims on cereals.<sup>68</sup> Another study showed that children do not dislike whole grains and, in fact, children like to eat healthy foods.<sup>69</sup>

When selecting bread, 84% of a leading sandwich chain's patrons who were asked, and who are not opposed to wheat bread, indicated that whole grain is important.<sup>70</sup> Forty-one percent of consumers are eating more whole grains, which is up from 34% in 1990.<sup>71</sup> Also, 71% of consumers claim they make "some" effort to consume whole grains.<sup>72</sup> However, 29% of the general population stated that their diets are deficient in whole grains.<sup>73</sup> In reality, 9 out of 10 consumers do not get enough whole grains.<sup>74</sup>

Studies also show that consumers are receptive to messages about nutrition and health. A recent survey found that 93% of Americans believe that some foods have health benefits that reduce their risk of disease or other health concerns and 85% are interested in learning more about such foods.<sup>75</sup> In addition, 65% of the general population has modified their diets to include or avoid some foods to eat healthier, while 74% stated that consumption of healthy, nutritious food is how they maintain a healthy balanced lifestyle.<sup>76</sup> These figures indicate that a

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<sup>67</sup> 82% of consumers responded that cereal that contains whole grain know that it is generally good for them. See, GMI Proprietary Study #1.

<sup>68</sup> GMI Proprietary Study #1.

<sup>69</sup> GMI Proprietary Study #2.

<sup>70</sup> GMI Proprietary Study #3.

<sup>71</sup> HealthFocus International, A National Study of Public Attitudes and Actions Toward Shopping and Eating – The 2003 HealthFocus Trend Report, 2003, page 7-3. (Attachment 14)

<sup>72</sup> The 2001 Gallup Study of Attitudes Toward and Knowledge of Cholesterol and Saturated Fats. (Attachment 4)

<sup>73</sup> Natural Marketing Institute, The Health and Wellness Trend Report, 2003, page 52. (Attachment 15)

<sup>74</sup> Cleveland, et al Dietary intake of whole grains, *Journal of American College of Nutrition* 19(3):331S-338S (2000).

<sup>75</sup> IFIC, Functional Foods: Attitudinal Research (2002) available at: [www.ific.org/research/FuncFoodsres02.cfm](http://www.ific.org/research/FuncFoodsres02.cfm). (Attachment 3)

<sup>76</sup> Natural Marketing Institute, The Health and Wellness Trend Report, 2003, page 45 and 51. (Attachment 16)

large percentage of the general population believes there is a definite connection between diet and health.<sup>77</sup>

Based on these results, consumers have incorporated the numerous messages about whole grain consumption, diet and health. However, as discussed in greater detail in the following section, although consumers understand that whole grain products are a component of the daily diet and recognize their connection with diet and health, consumers do not understand what whole grains are and where they can be found. Therefore, the difficulty lies with providing consumers with a tool to readily identify food products that contain dietarily significant amounts of whole grains so that the recommended daily servings and corresponding health benefits may be achieved.

## **I. Barriers to Consumption of Recommended Servings of Whole Grain**

### **1. Consumers are Confused About Whole Grains**

The most frequently cited barriers to increased consumption of whole grain foods by U.S. consumers are: (1) low awareness of their benefits, (2) inability to identify such foods in the marketplace and (3) unwillingness to sacrifice good taste.<sup>78</sup> It is clear from the recent consumer data discussed above that consumer awareness about the health benefits associated with whole grains is increasing and that many consumers are making efforts to increase whole grain consumption. However, the second and third cited reasons continue to be obstacles for consumer.

When consumers are asked specifically about certain whole grain products, often, their responses are incorrect. For example, many consumers believe that:

- whole grain bread must be brown;<sup>79</sup>
- “multi-grain” is the same as whole grain;<sup>80</sup>

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<sup>77</sup> *Id.* at 47. (Survey indicated that 37.9% agreed completely and 41.8% agreed somewhat that there is a definite connection between diet and health.) (Attachment 17)

<sup>78</sup> Kantor, L., et al., The Dietary Guidelines: Surveillance Issues and Research Needs, Choose a Variety of Grains Especially Whole Grains: A Challenge for Consumers, *Journal of Nutrition*, 131:473-486S (2001); and Adams, J., et al., Helping Consumers Achieve Recommended Intakes of Whole Grain Foods, *Journal of American College of Nutrition*, 19(3):339S-344S (2000).

<sup>79</sup> GMI Proprietary Study #4.

<sup>80</sup> GMI Proprietary Study #4.

- all cereals contain whole grain as long as they are not sugary;<sup>81</sup> and
- 80% of consumers believe that "many cereals provide good and/or excellent source of whole grains."<sup>82</sup>

These studies clearly demonstrate that consumers either do not know or are uncertain about which foods contain whole grains. In fact, many bread products that are brown do not contain whole grain, but instead are brown from the use of molasses or other sweeteners. Further, multi-grain products are not necessarily whole grain. Similarly, cereals that are not presweetened do not necessarily contain whole grains despite the majority of consumers attributing whole grain ingredients to these cereals. Finally, GMI estimates that only about 1/5 of ready to eat cereals contain enough whole grain to qualify for the whole grain health claim.

Although many consumers strongly believe that they know what classifies a food product as whole grain, these results demonstrate that many of their opinions are rooted in misperceptions.<sup>83</sup> Many products that consumers believe contain whole grain do not and those that do are being neglected because of the lack of easily identifiable means of signaling consumers to whole grain products. For consumers to increase their whole grain consumption, accurate and consistent information about which products contain whole grain must be provided.

## **2. Health Professionals Have Difficulty Conveying Information About Where to Find Whole Grain Products**

In 1996, GMI conducted a phone survey of military food service specialists who were asked about the availability of a range of whole grain food products.<sup>84</sup> Even though the military food service staff received an 8-week training course on nutrition, they were unable to correctly identify whole grain products. Of those surveyed, 89% believed they were serving whole grain bread at their facility when in fact only 24% were correct in identifying a true whole grain bread item.

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<sup>81</sup>GMI Proprietary Study #5.

<sup>82</sup> GMI Proprietary Study #1.

<sup>83</sup> GMI Proprietary Study #4.

<sup>84</sup> GMI Proprietary Study #6.

In 2003, the University of Minnesota conducted a survey of educators of USDA's Women Infant Children ("WIC") program.<sup>85</sup> A random national sample of WIC educators was mailed a survey, which was comprised of various scales and items to measure attitudes and practices related to encouraging clients to eat whole grain foods. A total of 306 surveys were returned. The majority of respondents indicated that they used a combination of criteria to identify whole grain foods: fiber content and whether the first ingredient on the ingredient list was whole grain. However, as discussed below, the variability in naming ingredients can result in consumer confusion regarding whole grain content. Also, consumers do not necessarily know how to correlate fiber level to whole grain content. Therefore, neither of these criteria are reliable indicators of whole grain content to consumers.

More than half of the WIC educators reported that they recommended more than 3 daily serving of whole grain to their clients and their attitudes toward the benefits of whole grain were very positive, but these educators also indicated that the difficulty of identifying whole grain foods was a barrier to consumption for their clients. On a scale from 1 to 6 (1=very difficult, while 6=easy), health professionals ranked the difficulty of helping clients identify whole grains as  $3.5 \pm 1.3$ .<sup>86</sup>

These studies indicate that whole grains present a challenge even for those who are more familiar with issues related to nutrition and health. In the absence of clear and consistent whole grain labeling, it is difficult for health professionals to assess the whole grain content of foods, and therefore they have difficulty conveying information about which products contain significant amounts of whole grain or how consumers can use food labels to identify whole grain foods. The whole grain descriptors proposed in this petition provide health professionals with an easy mechanism to assess whole grain content and communicate to their clients about how to identify products that contain dietarily significant amounts of whole grain.

### **3. Current Efforts to Identify Whole Grain are Insufficient**

Whole grain is unique in that it is a food ingredient that is consistently recommended by Federal agencies, health organizations, and health professionals, yet there is no readily accessible means for consumers to identify products that contain a dietarily significant level of whole grains. In fact, for

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<sup>85</sup> GMI Proprietary Study #7.

<sup>86</sup> Id.

ready to eat cereals, whole grain is one of the top 5 items of nutrition that drive purchasing decision.<sup>87</sup> However, whole grain is the only one of those 5 items for which there is no simple and consistent labeling allowing consumers to identify its presence, which further illustrates the difficulty consumers face when attempting to make sound nutritional decisions regarding diet.

Indeed, the numerous pamphlets, leaflets, and information sheets published by Federal Agencies, food companies and other organizations are indicative of the complexity associated with identifying products that contain whole grain. For example, USDA published "Get on the Grain Train" in May 2002 to assist consumers in understanding and obtaining whole grains in their diets.<sup>88</sup> Food companies, such as GMI and Quaker have published separate pamphlets and information sheets that attempt to provide consumers with information about whole grain products.<sup>89</sup> The American Dietetic Association also produces a fact sheet on whole grain that was sponsored by Post® Cereals.<sup>90</sup>

Given the absence of any defined term, the predominant advice given to consumers to assist them in identifying whole grain foods is to look at the ingredient statement of the product. However, the ingredient statement alone is not necessarily adequate for identifying foods that contain dietarily significant amounts of whole grain. The ingredient list may under- or over-convey the actual whole grain content to a consumer, because whole grain is not always declared in the same manner. For example, ingredient lists often include "rolled oats," which does not immediately convey to the consumer that it is a whole grain ingredient. Further, "whole grain wheat" is sometimes declared as such, but sometimes is simply labeled as "whole wheat." This can result in consumer confusion regarding the whole grain content of a food. Similarly, whole grain's position in the ingredient list may under- or over-convey whole grain content.

The descriptors for whole grain proposed in this petition clearly remedy this confusion by establishing defined claims about whole grain content to help Americans easily identify foods that are significant sources of whole grain across a variety of categories. Consistent established standards along with permitted claims will provide an incentive for manufacturers to increase the whole grain

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<sup>87</sup> GMI Proprietary Study #1.

<sup>88</sup> USDA, Get on the Grain Train, May 2002. (Attachment 6)

<sup>89</sup> GMI produces an information sheet entitled, "Go with the Grain," while Quaker also publishes a pamphlet on whole grain. (Attachments 18 and 19, respectively)

<sup>90</sup> American Dietetic Association, Whole Grain For Healthful Eating Recipe, 2000. (Attachment 7)

content of their products and avoid opportunity for misleading labeling due to lack of standardized definitions.

## **J. Proposed Descriptors for Whole Grain – “Good Source,” “Excellent Source,” and “Contains/With”**

### **1. Whole Grain Levels for Descriptors**

The definitions of the descriptors requested in this petition represent dietarily significant amounts of whole grain and are consistent with existing whole grain health claims, the Healthy People 2010 Objectives, the Food Guide Pyramid, and Dietary Guidelines. In fact, when used in conjunction with dietary guidance statements or health claims, the whole grain descriptors will supplement consumers' understanding by drawing a connection between the dietary guidance and foods that contain dietarily significant levels of whole grain.

The proposed whole grain descriptors are:<sup>91</sup>

Excellent source of whole grain: The terms “excellent,” “rich in,” or “high in” whole grain(s) may be used on the label and in labeling of foods provided that the food contains 16g or more of whole grain per labeled serving.<sup>92</sup>

Good source of whole grain: The terms “good source,” “contains,” or “provides” whole grain(s) may be used on the label and on the labeling of foods provided that the food contains 8g to 15g of whole grain per labeled serving.

Made with whole grain: The term “made with” whole grain(s) may be used on the label and on the labeling of foods provided that the food contains at least 8g of whole grain per labeled serving.

For purposes of these claims, whole grains are defined as set forth in Section C of this petition. As previously stated, whole grain includes all edible parts of the

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<sup>91</sup> See, Attachment 1 for complete proposed regulation.

<sup>92</sup> Whole grain content claims should be based on the amount of whole grain per labeled serving of the food. This will result in greater and more consistent whole grain content per serving as understood by the consumer, and will allow them to better coordinate their whole grain intake with the other labeled nutrients. We recognize that many claims are based on the reference amount customarily consumed (“RACC”), which could also be an appropriate basis for determining whole grain content.

grain: the bran, germ and endosperm. Food ingredients that are considered whole grain have been classified by USDA and include, among others, barley, buckwheat, corn, oats, rice, wheat and rye.<sup>93</sup>

## **2. Whole Grain Levels are Supported by the Dietary Guidelines and Scientific Data**

The Food Guide Pyramid and Dietary Guidelines recommend 6-11 servings daily of grain products, and more specifically, recommend that at least several of those servings be from whole grain. The USDA defines a "grain serving" as "the grams of grain product containing 16 grams of flour."<sup>94</sup> Accordingly, a "whole grain serving" would contain 16 grams of whole grain. Thus, a food that is identified as an excellent source of whole grain would equal one full serving of whole grain and satisfy one-third of the minimum daily recommended intake.

The definition of 8g of whole grains for a "good source" claim assures an achievable and dietarily significant amount of whole grain in a serving of food. It allows manufactures to increase the whole grain content without so affecting taste that consumers will reject the foods. This is especially important for foods with smaller serving sizes. As noted above, consumers' unwillingness to sacrifice good taste is a frequently cited barrier to increased consumption of whole grain foods.<sup>95</sup> Also, manufacturers that may not be able to reach the full 16g amount are still provided an incentive to increase the whole grain content of the food. In addition, consumers consuming six servings of grain products (the minimum number of grain products servings recommended in the Food Guide Pyramid and Dietary Guidelines) that are identified as a "good source" of whole grains would meet the recommendation to consume at least three servings of whole grain foods daily.<sup>96</sup>

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<sup>93</sup> Food Ingredients Classified as Whole Grain in USDA's Pyramid Servings Database include an extensive list of grains that may be considered whole grains. *See*, Cleveland, L.E., et al., Dietary intake of whole grains, *Journal of American College of Nutrition*, 19(3):331S-338S (2000).

<sup>94</sup> USDA, 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).

<sup>95</sup> Adams, J.F., Helping consumers achieve recommended intakes of whole grain foods, *Journal of American College of Nutrition*, 19(3):339S-344S (2000).

<sup>96</sup> *See*, Welsh, S., et al., Achieving dietary recommendations: whole grain foods in the food guide pyramid, *Critical Reviews in Science and Nutrition*, 34:441-451 (1994); and American Dietetic Association, Get the Whole Grain Picture, available at: [http://www.eatright.org/print/index\\_18475.cfm](http://www.eatright.org/print/index_18475.cfm) (Attachment 9). This definition is also consistent with the definitions of whole grain breakfast cereal servings used by Willet and Jacobs in their

The proposed whole grain claims provide a meaningful solution for consumers to meet the daily recommended servings of whole grains. Using the proposed claims, consumers have an easy way of keeping track of their daily intake. For example, a typical diet may consist of the following items:

Breakfast	Ready-to-eat cereal that meets the excellent source of whole grain claim	1 serving
Lunch	Sandwich with 2 slices of whole grain bread that each meet the good source claim	1 serving
Snack	Granola Bar that meets the good source whole grain claim	½ serving
Dinner	Side dish such as brown rice or dinner roll that meets the good source whole grain claim	½ serving

These simple descriptors allow consumers to readily identify and count the number of servings that are consumed daily and assist them in meeting the recommended whole grain servings.

### 3. Consumers Respond Positively to the Whole Grain Descriptors

The whole grain claims proposed in this petition provide consumers with a mechanism to act upon the health recommendation provided by DHHS and USDA by identifying products that will help them achieve their dietary and

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research on whole grain consumption and its relationship to health outcomes. Assessment of whole grain intake using the Willet semi-quantitative food frequency questionnaire ("SFFQ") in population-based epidemiological studies adopted an approach originally developed by Jacobs in 1998. The list of breakfast cereals with  $\geq 25\%$  whole grain or bran content by weight was classified as whole grain. Under this assessment, a 30-gram serving of breakfast cereal (the RACC for many breakfast cereals) classified as whole grain by Jacobs would provide 7.5 g of whole grain, which is consistent with the 8 g proposed for the "made with" and "good source" claims in this petition. See, Liu, S., et al., Whole Grain Consumption and Risk of Coronary Heart Disease; Results From the Nurse's Health Study, *American Journal of Clinical Nutrition*; 70:412-9 (1999); and Jacobs, D.R., et al., Whole Grain Intake May Reduce the Risk of Ischemic Heart Disease Death in Postmenopausal Women: The Iowa Women's Health Study, *American Journal of Clinical Nutrition*, 68:248-57 (1998).

health goals. In particular, the whole grain descriptors have been strongly supported by consumers. Generally, consumers believe content claims are more important than health claims. In a recent survey, 53% of consumers find good/ excellent source claims extremely or very important on labels, while only 41% find health claims extremely or very important.<sup>97</sup>

For whole grain claims, a consumer study indicated that the claims "excellent source," "good source," and "contains/made with" were interesting, believable and motivating.<sup>98</sup> When questioned about various food label descriptors, the largest proportion of consumers reported that "contains whole grains" (37%) would greatly increase their purchase interest followed by "high fiber" (30%) and "cholesterol free" (30%).<sup>99</sup>

#### **4. Establishing the Proposed Descriptors for Whole Grain is Consistent with FDA's Consumer Health Initiatives**

Recently, FDA has focused its attention and resources on consumer health programs such as CHIBN Initiative and the Obesity Workshops. These programs have placed among FDA's priorities the importance of providing science-based information to consumers. By informing consumers about the consequences of health and nutrition, consumers are better equipped to improve their health and prevent disease. The actions requested in this petition are consistent with these goals and provide a prompt response to these consumer health initiatives.

It is entirely within FDA's authority and mandate to ensure that food labels convey truthful and non-misleading information to consumers. FDA has long acknowledged the need for regulations to define terms of particular benefit to consumers that appear on food labels. For example, FDA defined the term "fresh" when promulgating nutrition regulations, even though it was not a nutrition related term.<sup>101</sup> FDA noted that it would be useful to prevent consumer confusion.<sup>102</sup> The proposed whole grain content claims will similarly serve to

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<sup>97</sup> HealthFocus International, A National Study of Public Attitudes and Actions Toward Shopping and Eating – The 2003 HealthFocus Trend Report, 2003, page 5-19. (Attachment 20)

<sup>98</sup> GMI Proprietary Study #8.

<sup>99</sup> The 2000 Gallup Study of Attitudes Toward and Knowledge of Cholesterol and Saturated Fats. (Attachment 4)

<sup>100</sup> General Mills Proprietary Study #9.

<sup>101</sup> 21 C.F.R. § 101.95.

<sup>102</sup> 58 Fed. Reg. 2302 at 2401-2402.

prevent consumer confusion, by providing a simple and consistent standard for food labeling. The FDA also explained in the 1993 final rule that a definition for fresh and its related terms is necessary because of the consumer confusion that has resulted from its misuse and "that a regulatory definition will discourage such misuse and will allow the Agency to efficiently enforce the misbranding provisions of the Act, particularly Section 403(a), when the term is misused."<sup>103</sup>

Establishing these definitions also fits squarely with FDA's stated objective of increasing enforcement activities regarding consumer labeling.<sup>104</sup> By establishing a simple and consistent standard against which to evaluate whole grain label claims, FDA will better be able to ensure labels are accurate. Also, by publishing a consistent standard, FDA will encourage manufacturers to produce foods that satisfy the requirements of the claim. A consistent labeling standard will also make it easier for health professionals to guide consumers in their healthy food choices.

A substantial body of scientific evidence supports the descriptors for whole grain. There is a significant amount of scientific data attributing positive health benefits to whole grain. In addition, the proposed levels for the nutrient descriptors are based on sound scientific data and dietary guidelines established by public health agencies within DHHS and USDA. The whole grain descriptors take into account and complement the recommendations put forth by these public health agencies. Finally, consumer studies indicate that Americans are receptive to information about whole grain consumption, diet and health and these claims facilitate their goals. These data provide adequate evidence to support the use of these claims and the public health benefits that will be achieved through greater awareness of whole grain content in foods.

As discussed above, consumers are continually reminded through the health claims about products that contain whole grains and the numerous dietary guidance recommendations about whole grain consumption. However, consumption is still significantly below daily recommended servings. This is due, in part, to consumers' confusion about which products contain whole grains.

The two-step process establishing the proposed descriptors for whole grain, which is discussed in greater detail in the following section, provides immediate access to a mechanism to easily identify foods that contain a dietarily

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<sup>103</sup> 58 Fed. Reg. 2302 at 2402.

<sup>104</sup> Announcement of the CHIBN Initiative, December 18, 2002.

significant amount of whole grain. Considering the wide variety of foods that are, or could be, formulated to contain at least 8 grams of whole grain per serving (e.g., breads, pasta, breakfast cereals, side dishes, main meals and dinners, crackers, snack bars), it is likely that manufacturers will respond to the availability of these claims by increasing products' whole grain content and, thereby, creating a greater variety of whole grain products on the market. Adoption of these claims will encourage increased consumption of whole grain foods and work towards eliminating consumer confusion about which products contain whole grains.

#### **K. Whole Grain Claims Should be Implemented in a Two-Step Process – Guidance Document then Rulemaking**

As proposed, the descriptors for whole grain are supported by a significant body of data and characterize in simple terms food products that contain dietarily significant amounts of whole grain. These descriptors are consistent with and complement existing FDA health claims and USDA dietary guidance. Indeed, these whole grain claims provide an easily identifiable means for consumers to connect the dietary guidance regarding whole grain intake with products that contain this valuable substance.

Increasing scientific evidence indicates that there are an abundance of health benefits associated with whole grain consumption. In this era of chronic disease, the alarming rise in obesity, and other public health issues, implementing tangible solutions for consumers to address these ailments is critical. The two-step process proposed in this petition provides timely response so that consumers may begin modifying their behavior and incorporating beneficial eating habits to obtain positive health results.

To implement these whole grain claims, the Agency should proceed in a two-step process that consists of, first, issuing a guidance document, then, second formalizing the policy through rulemaking procedures. Guidance documents provide a less resource intensive process while maintaining Agency oversight of the regulated industry. More importantly, in light of the public health need and the consumer health initiatives underway at FDA, issuance of a guidance document addresses in a timely manner the rising concerns regarding nutrition and health.

The guidance document should consist of the descriptors "excellent source," "good source," and "made with" for whole grain as proposed in this petition. Additionally, the guidance document should articulate an updated policy with respect to the use of the term "whole grain." In the preamble discussion to a

previous rulemaking document, FDA stated that whole grain may be interpreted as an implied nutrient content claim for fiber.<sup>105</sup> This position has discouraged manufacturers from communicating to consumers regarding whole grain, thereby providing no incentive for manufacturers to increase whole grain content in foods. In light of the mounting scientific evidence in favor of the health benefits associated with whole grain, FDA's outdated position about a presumed exclusive relationship between whole grain and fiber should be revised to reflect the current science and dietary guidance by recognizing the entire whole grain as a beneficial and unique substance, and providing a simple and consistent labeling message for manufacturers to use to communicate whole grain content to consumers.

Subsequent to the issuance of the guidance document, FDA may formalize its policy on the descriptors for whole grain by conducting informal rulemaking. In Attachment 1, proposed regulations for the nutrient descriptors are provided that establish appropriate whole grain levels to qualify for the claims, as well as corresponding compliance and test methodologies.

Through the guidance document, the Agency may use its enforcement discretion to ensure that food manufacturers are properly declaring the claims on their food labels. Compliance, which is discussed in more detail in the following section, will be determined using fiber as a surrogate to evaluate whether the product meets the requisite whole grain levels for the declared claim. Fair and regulated claims are essential for consumers to adopt and understand new labeling claims. Indeed, the purpose of the nutrient descriptors is to assist consumers in identifying food with dietarily significant amounts of whole grain. As FDA recognized in stressing the importance of enforcement to the CHIBN objectives, without vigilant enforcement of inappropriate use of the claims, the benefit to the public health obtained by increased consumption of whole grains will not be achieved.

Implementation of the nutrient descriptors for whole grain through the two-step process recognizes that public health is a priority and immediate action must be taken to provide consumers with direct and tangible benefits. Initiating the process through the guidance document allows consumers immediate access to the health and nutrition information of whole grains and allow them to apply

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<sup>105</sup> In the preamble to FDA's regulation implementing NLEA, FDA discussed the issue of "single nutrient implied claims." In its discussion, FDA stated its position that statements such as "contains oat bran" or "contains whole wheat" "would be nutrient content claims because they call attention to the fact that the product has been made with an ingredient that contains a valuable nutrient [fiber]," although FDA stated that it would evaluate such claims on a case-by-case basis. (58 Fed. Reg. 2302 at 2370).

the new information in their daily diets, while rulemaking, a more labor intensive process, will follow. The two-step process would allow FDA to issue its standards in advance of or in conjunction with the 2005 Dietary Guidelines, thereby reducing the potential for confusion in the marketplace.

## **L. Proposed Compliance Method for Whole Grain Descriptors**

GMI proposes that compliance with the whole grain descriptors may be initially determined based on the fiber content of the product. While it is undeniable that the benefits of whole grain go beyond its fiber content, fiber is a useful analytical tool for determining whole grain content. This approach is consistent with the methodology proposed by GMI in its whole grain health claim notification in 1999, which the Agency accepted as providing reasonable assurance that the whole grain content is as claimed on the label.

### **1. Determining Compliance for Products that Contain a Single Source of Whole Grains**

For products that are composed of a single source of whole grain, compliance may be evaluated based on fiber level for that specific ingredient. For example, on the food label, the ingredient list will indicate what food component makes up the whole grain claim (e.g., wheat flour, oats, etc.). Fiber contents for whole grain food ingredients are available from USDA's nutrient database,<sup>106</sup> and the fiber levels of several common whole grains are identified in the following table.

#### **Fiber Content of Common Whole Grain Sources**

<b>Whole Grain</b>	<b>Fiber Content (g/100g)</b>
Wheat flour	12.2 <sup>107</sup>
Rye flour	18.6
Rice, brown	4.6
Corn flour and meal, hominy, and grits	9.8 (weighted average)
Oats	10.6

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<sup>106</sup> Fiber Content from USDA nutrient database available at [http://www.nal.usda.gov/fnic/foodcomp/cgi-bin/list\\_nut\\_edit.pl](http://www.nal.usda.gov/fnic/foodcomp/cgi-bin/list_nut_edit.pl).

<sup>107</sup> Wheat flour includes wheat cereal consumption data. The fiber content, however, is for wheat flour and has not been adjusted to reflect wheat cereal.

Using the fiber content for that specific ingredient, the Agency may determine the appropriate fiber level that the food product must meet in order to be in compliance with the whole grain content identified for the specific descriptor claimed on the food label.

#### Example 1: Single Ingredient Whole Grain Wheat Product

A whole grain bread label declares “excellent source of whole grain” and indicates in its ingredient list “whole wheat flour.” The “excellent source of whole grain” claim requires that the product contain at least 16g of whole grain per labeled serving, and, using fiber as a surrogate to determine whole grain levels, the product must meet a fiber per serving value of:

$$\begin{array}{rcccl} 16 \text{ g of whole grain} & & 12.2 \text{ g fiber/100 g} & & 1.95 \text{ g fiber} \\ \text{for the} & \text{X} & \text{whole wheat flour} & = & \text{must be present in} \\ \text{excellent source} & & & & \text{one serving of the} \\ \text{claims} & & & & \text{product bearing the} \\ & & & & \text{claim} \end{array}$$

For compliance purposes, FDA may use the 1.95 g of fiber to evaluate whether the food product meets the requisite whole grain level associated with the claim declared on the labeling. In addition, a manufacturer may voluntarily provide other evidence to demonstrate that the product is in compliance.

#### Example 2: Single Ingredient Whole Grain Brown Rice Product

A whole grain cereal label declares “excellent source of whole grain” and indicates in its ingredient list “whole grain brown rice.” The “excellent source of whole grain” claim requires that the product contain at least 16g of whole grain per labeled serving, and, using fiber as a surrogate to determine whole grain levels, the product must meet a fiber per serving value of:

$$\begin{array}{rcccl} 16 \text{ g of whole grain} & & 4.6 \text{ g fiber/100 g} & & 0.74 \text{ g fiber} \\ \text{for the} & \text{X} & \text{whole grain brown} & = & \text{must be present in} \\ \text{excellent source} & & \text{rice} & & \text{one serving of the} \\ \text{claims} & & & & \text{product bearing the} \\ & & & & \text{claim} \end{array}$$

For compliance purposes, FDA may use the 0.74 g of fiber to evaluate whether the food product meets the requisite whole grain level associated with the claim declared on the labeling. In addition, a

manufacturer may voluntarily provide other evidence to demonstrate that the product is in compliance.

## **2. Determining Compliance for Products that Contain a Blend of Whole Grain Sources**

Because the fiber content of different whole grains varies, a different approach has been developed to address products that contain a variety of different grains and declare a whole grain descriptor. Specifically, GMI has developed a fiber content for a whole grain blend (identified in the table below) that represents a weighted average of the grains most prevalent in the U.S. diet. To develop this number, the fiber contents are multiplied by the percentage each grain represents of the overall whole grain intake, based on the USDA consumption data. The resulting fiber content to use as a marker for the whole grain blend is 11.1g of fiber/100g of whole grain blend.

### Whole Grain Blend Fiber Content

Whole Grain	Fiber Content Based on the Weighted Average (g/100g)	Fiber Content <sup>108</sup> (g/100g)	Percentage of whole grain intake	Consumption pounds per capita <sup>109</sup>
Wheat flour	8.97	12.2	73.5% <sup>110</sup>	146.1
Rye flour	0.06	18.6	0.3%	0.6
Rice, brown	0.51	4.6	11.0%	21.9
Corn flour and meal, hominy, and grits	1.21	9.8 (weighted average) <sup>111</sup>	12.3%	24.4
Oats	0.28	10.6	2.6%	5.1
Barley	0.05	13.7 (average of barley flour and unmilled barley) <sup>112</sup>	0.4%	0.7
<b>Whole Grain Blend</b> (g of fiber/100g)	<b>11.1</b> <sup>113</sup>			

<sup>108</sup> Fiber Content from USDA nutrient database, found at [http://www.nal.usda.gov/fnic/foodcomp/cgi-bin/list\\_nut\\_edit.pl](http://www.nal.usda.gov/fnic/foodcomp/cgi-bin/list_nut_edit.pl).

<sup>109</sup> Pounds per capita consumption data is for 2001, the most recent year available, in USDA's National Agricultural Statistics Service (USDA-NASS) *Agricultural Statistics 2003*, available at <http://www.usda.gov/nass/pubs/agr03/acro03.htm>.

<sup>110</sup> Wheat flour includes wheat cereal consumption data. The fiber content, however, is for wheat flour and has not been adjusted to reflect wheat cereal.

<sup>111</sup> For corn, a weighted average was developed that included corn flour, hominy, and grits and was based on the fiber levels (corn flour 11.5g/100g, hominy and grits 5.2 g/100g) and consumption (corn flour 17.8 pounds (9%), hominy and grits 6.6 pounds (3.3%)).

<sup>112</sup> For barley, a straight average of the fiber levels (whole barley 17.8g/100g, and barley flour 10.1g/100g) was calculated.

<sup>113</sup> This figure has been rounded from 11.08 g of fiber/100 g.

### Example 3: Product that Contains a Blend of Whole Grains

For a cereal product that identifies on its label a blend of whole grains and includes the proposed "good source of whole grain" claim on the label, the fiber content of the product should be

$$\begin{array}{rcl} 8 \text{ g of whole grain} & & 11.1 \text{ g fiber/100 g} \\ \text{for the} & \times & \text{whole grain blend} \\ \text{good source claim} & & \end{array} = \begin{array}{l} 0.89 \text{ g of fiber} \\ \text{must be present in} \\ \text{the product} \\ \text{declaring the claim} \end{array}$$

For compliance purposes, FDA may use the 0.89 g of fiber to evaluate whether the food product meets the requisite whole grain level associated with the claim declared on the labeling. In addition, a manufacturer may voluntarily provide other evidence to demonstrate that the product is in compliance.

The representative fiber content for the whole grain blend is an accurate formula for determining whether the product complies with the whole grain claims. These fiber test results should serve as compliance checks for whole grain content. The results will provide FDA with reasonable assurance that the declared whole grain content is present in the food. Nonetheless, a company should always be afforded an opportunity to present other supporting data or documentation establishing the whole grain content of the product.

#### **M. Conclusion**

Based on the foregoing, GMI respectfully requests that the FDA develop whole grain descriptors as proposed herein along with the proposed compliance mechanism. The whole grain claims will assist consumers in identifying whole grain products thereby increasing their consumption, which will contribute added health benefits. These actions are consistent with and promote the current consumer health initiatives underway at FDA.

### III. Environmental Impact

Petitioner hereby claims a categorical exclusion from the environmental assessment requirement pursuant to 21 C.F.R. §§ 25.30(h) and 25.30(k).

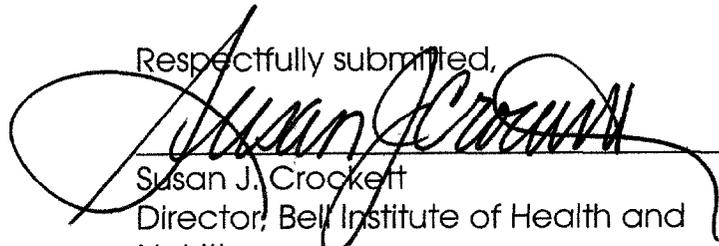
### IV. Economic Impact

An economic impact analysis is not required at this time.

### V. Certification

The undersigned certifies that, to the best of the undersigned's knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes favorable and unfavorable representative information relevant to the petition.

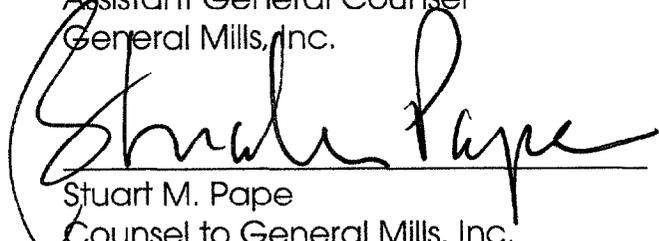
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