



April 17, 2006

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

Docket No. 2006D-0066

Dear Food and Drug Administration,

Members of the AACC International Task Force on Defining Whole Grains in Food are responding to the announcement in the Federal Register, vol. 71, No. 33, Friday, February 17, 2006 regarding Draft Guidance for Industry and FDA staff: Whole Grains Label Statements: Availability.

The Task Force, chaired by Julie Miller Jones from the College of St. Catherine, is comprised of academics, industry, non-profit, and government participants trying to arrive at the best possible labeling, research and communication agendas on the whole grain issue. Furthermore, the work of the Task Force is strengthened by smaller expert task forces convened to deal with issues specific to processing of traditional whole grain foods barley, bulgur, and liming of corn (nixtimalization).

AACC International (formerly the American Association of Cereal Chemists) is the premier worldwide organization for advancing grain science and technology by creating, interpreting, and disseminating cereal information and providing personal and professional development opportunities for its members. Worldwide membership in AACC Intl. includes over 3500 scientists representing industry, academia, and government.

First, the AACC Intl. Task Force on Defining Whole Grains wishes to state that we are fully in support of labeling and FDA promulgation of rule-making that will

- (1) Encourage increased consumption of whole grains for better health as indicated in the Dietary Guidelines for Americans;
- (2) Give the consumer greater clarity in the marketplace in order to select whole grain foods;
- (3) Eliminate or avoid multiple standards that will paralyze consumers and manufacturers;
- (4) Support and encourage foods made with a blend of whole and enriched grains, but that contribute dietarily significant whole grain content – not just foods that are entirely or almost entirely manufactured with whole grains.

Second, we would like to speak to various aspects of the guidance under Part III, which we have done in the pages following this cover letter.

Dr. Julie Miller Jones and Dr. Stuart Craig are available to meet with FDA to discuss further the AACC International's position on these matters and to assist FDA in all ways possible in crafting consumer-friendly, useful rule-making on whole grains. An appointment may be set up by contacting Susan Kohn at AACC International.

Best regards,

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President, AACC International

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AACC International Comments on Part III of the Draft Guidance on Whole Grain Label Statements

The AACC International Task Force on Defining Whole Grain in Foods has the following comments and positions on Part III of the FDA's Draft Guidance:

- 1. We are pleased that the definition of whole grain used in the guidance is the one provided by AACC International's past deliberations.** We agree that cereal grains meeting these properties will always be whole grains. However, we also feel strongly that minimally-processed bulgur wheat and nixtimalized corn should also be considered whole grains, even though small amounts of the kernel are lost when using traditional processing methods. These processes have been followed for millennia and both bulgur wheat and masa (the end product of nixtimalization) have long been regarded as whole grain and nutritionally are believed to function as whole grain. Two other grains, barley and durum wheat (as grano) that have traditionally been lightly pearled to assist in removal of their inedible hulls should also be considered whole grain – as long as such pearling is kept to minimum, defined levels. (See question 5). Thus the definition of whether an ingredient or food is a whole grain should make some allowance for slight losses that occur through traditional processing methods.
- 2. We agree with the list of grains that are included as cereal grains. However the AACC Intl. task force on Defining Whole Grains in Foods has compiled a more comprehensive list,** included below, of cereals and pseudocereals that, when consumed in whole form (including the bran, germ and endosperm) are considered whole grains. Scientific consensus may add other grains to this list in the future.

We also would like to go on record with the following definition of cereals and pseudocereals. Cereals are generally considered to be the seed heads of grasses from the Poaceae (synonymous with Gramineous) family. Pseudocereals are seed heads of a number of different species of plants that do not belong to the grass family and do not include legumes or oilseeds. The Task Force decided that the pseudocereals should be included with the cereals because the grain heads of pseudocereals are used in the same traditional ways that cereals are used, such as in the making of bread, starch staples and side dishes. In addition, the overall macronutrient composition (proportions of carbohydrate, protein and fat) of cereals and pseudocereals is similar.

True Cereals	Scientific name
Wheat including spelt, emmer, farro, einkorn, kamut, durums	<i>Triticum spp.</i>
Rice, African rice	<i>Oryza spp.</i>
Barley	<i>Hordeum spp.</i>
Corn (Maize, Popcorn)	<i>Zea mays</i>
Rye	<i>Secale cereale spp.</i>
Oats	<i>Avena spp.</i>
Millets	<i>Brachiaria spp.; Pennisetum spp.; Panicum spp.; Setaria spp.; Paspalum spp.; Eleusine spp.; Echinochloa spp.</i>
Sorghum	<i>Sorghum spp.</i>
Teff (tef)	<i>Eragrostis spp.</i>
Triticale	<i>Triticale</i>
Canary Seed	<i>Phalaris arundinacea</i>
Job's Tears	<i>Coix lachrymal-job</i>
Fonio, Black Fonio, Asian Millet	<i>Digitaria spp.</i>
Pseudocereals	Scientific name
Amaranth	<i>Amaranthus caudatus</i>

Buckwheat, Tartar Buckwheat
Quinoa

Fagopyrum spp
*Chenopodium quinoa Willd - is generally
considered to be a single species within the
Chenopodiaceae*

Wild rice

Zizania aquatica

3. We agree that legumes such as soybeans and chickpeas are not whole grains.
We agree that products derived from legumes, nuts, seeds and roots, while potentially offering wonderful nutritional qualities, are not whole grains. We base this decision on differences in the overall macronutrient composition. Legumes contribute more protein and more fat than cereal grain and have different amino acid profiles. Cereals are limited in lysine and legumes provide adequate lysine but are limited in methionine and sulfur amino acids.

4. We agree that corn meal and corn flour that are degerminated or bolted are not whole grain.
We also agree that corn flour that has had all the pericarp removed is not whole grain. The AACC-Intl Expert Task Force on Corn Nixtimalization is considering the effects of this mode of processing on the whole grain nature of the corn, as nixtimalized corn products are a significant contributor to the whole grain intake of certain ethnic subcultures and age groups in the US and we want to be certain that we can recognize these legitimate sources. Some nixtimalization processes leave a significant amount of pericarp, but during processing some pericarp (part of the bran and phenolics) is solubilized into the alkaline wash and lost. The Task Force is still in the process of determining what degree of loss is acceptable when corn is treated with lime (calcium hydroxide) in the traditional nixtimalization process. The nixtimalization process is known to improve the nutritional bioavailability of niacin, protein and certain essential amino acids and to significantly reduce levels of mycotoxins when present. The process also increases the calcium levels of the food. We urge the FDA to delay making a final decision on nixtimalized corn until the AACC Intl. Expert Task Force has completed its work.

5. We agree that dehulled barley is a whole grain and that naked barleys are also whole. An AACC Intl. Expert Task Force on Barley is recommending to the AACC Intl. Board that barley will be considered whole grain if the barley is a naked variety or if a covered barley has been hulled (also called de-hulled or lightly pearled).

In addition, the AACC International Task Force on Whole Grains agrees with FDA that bulgur should be considered a whole grain, even though very small amount of bran and germ are lost in the time-honored process of making bulgur. We recommend that lightly pearled barley, grano (lightly pearled wheat) and bulgur that has been minimally processed be classified as whole grains. The AACC Intl. Expert Task Force on Bulgur is working to define the extent of loss that is acceptable in whole-grain bulgur, and we urge the FDA to delay any decision until this information is available.

6. We agree that oats and oat products made from the entire oat groat are whole grains. The AACC Intl. Task Force notes that traditional processing of raw oats results in whole grains even though it uses heat to inactivate enzymes, and decrease moisture in the oat groat. Steel cut oats (also called Irish or Scottish oats), rolled oat flakes, quick and instant oats and whole oat flour made from the entire oat groat are whole grains. Oat bran and oat flour which has had a portion of the germ or bran removed are not whole grains.

7. We agree that 100% whole grain products be labeled as such only if the grain portions they contain are whole grain with the following allowance which has already been covered in 21 CFR 136.110(c)(18), while 21 CFR 136.110(c)(11) by setting the standard of identity for whole wheat bread. Federal regulations allow for "nonwheat flours, nonwheat meals, nonwheat grits, wheat and nonwheat starches, and of which may be wholly or in part dextrinized, dextrinized wheat flour, or any combination of 2 or more of these, if the total quantity is not more than 3 parts for each 100 parts by weight of flour used." Vital wheat gluten is a special case. Bakers add gluten in

quantities consistent with good manufacturing practice surpassing the three parts per 100 level, in order to achieve the appropriate functionality of whole grain breads. If the option of gluten is overly restricted, removed or penalized, fewer commercial products would be available to consumers. The three parts per 100 level would still be the appropriate reference for bran toppings, corn starch used as a release agent, etc.

This Task Force is still working on several other issues, including whether there should be any minimum level of whole grain content in foods labeled 100% whole grain. We are reviewing data that shows that products with low levels of whole grain content make a sizable contribution to overall whole grain consumption.

8. **We agree that label designations such as ‘whole durum wheat flour’ when used on the ingredient statement help the consumer know that the product is whole grain.** We would go further to recommend that all whole grain flours be so labeled e.g., whole oats (oatmeal) etc. (See recommendation 11 on ingredient statement declarations)
9. **We agree that the standards of identity for whole wheat bread [21 CFR 136.180] and macaroni products, including spaghetti and vermicelli [21 CFR 136.180] exist and help the consumer identify whole grain products.**
10. **We support FDA's goal of clarifying the types of wholegrain labeling statements allowed on food products, in order to help consumers make wise choices in accordance with science and with the Dietary Guidelines.** The AACC Intl. Task Force on Defining Whole Grains feels strongly that such clarification must begin with consensus on the amount of whole grain that is dietarily significant.

Based on the rationale explained below, this Task Force supports the use of 48g as a recommended minimum daily intake of whole grains. We also support incorporating this daily intake recommendation into labeling of whole grains. We recommend that, if a product label states “xx grams of whole grains” as suggested in the FDA's Draft Guidance, that the phrase “at least 48 grams are recommended daily” should be included to provide context.

Recent studies quantifying whole grain intake, including those below, confirm that the effects of whole grain appear to be independent of the whole grain concentration of the food source. These findings suggest that products containing less than 51% whole grain by weight can also contribute to the observed health benefits of whole grain. This approach allows consumers to make healthy choices, while avoiding labeling standards that are overly restrictive and that may exclude a substantial number of helpful foods which contain whole grains but do not meet a specific threshold.

Determining a Dietarily Significant Amount of Whole Grain – a Brief Review

Alteration of Risk with Ingestion of Whole Grain

Ingestion of between one and three servings of whole grain has been shown to reduce the risk of a number of chronic diseases. The precise amount of whole grains associated with reduced risk varies with the disease, the population and the method used to determine the amount of whole grain. The following review outlines the research approaches used to quantify whole grain levels in the scientific literature.

As little as one serving of whole grain per day has been shown to be effective in some studies for reducing risk of chronic disease. One serving per day decreased ischemic stroke by 30-36% in the Harvard Nurses' Health Study (N=75,521) (Liu et al, 2000). Additionally, one serving of whole grain breakfast cereal per day reduced the risk of cardiovascular disease mortality (in the over 5 years of the study) in over 86,000 male physicians by 20% compared to men who rarely consumed wholegrain breakfast cereals (Liu et al, 2003).

Similarly, consuming three servings per day of whole grain has been shown in other studies as being associated with decreased disease risk. Examination of the Nurses' Health Study (NHS)(Liu et al, 1999; 2000) revealed the risk of diabetes was reduced by 27%, and the risk of heart disease reduced by 25% among women who consumed the most whole grain foods (median intake 2.7 servings/day) compared to those with the lowest intake of whole grains (median intake 0.13 servings/day). Furthermore, women with the highest whole grain consumption (2.7 servings/day) consistently weighed less, and gained less weight over time (Liu et al, 2003).

In the Iowa Women's Health Study (N=35,988) Type 2 diabetes risk was decreased by 21% in the quintile eating the most whole grain (median intake of 3.0 servings of whole grain per day) compared to the lowest quintile (median intake of 1 serving/week) (Meyer et al, 2000). In the Health Professionals Follow-Up Study (N=42,898) (Fung et al, 2002), there was a 30% decrease in risk of diabetes in the highest quintile of whole grain intake (3.2 servings/day) compared to the lowest quintile (0.4 servings/day).

Steffen and colleagues (2003) reported a 23% decreased risk of all-cause mortality, and a 28% decreased risk of incident coronary artery disease comparing mean whole grain intakes of 3 servings/day against 0.1 serving/day in the Atherosclerosis Risk In Communities cohort (N=15,792).

More recent studies on the health benefits of whole grain have attempted to quantify daily whole grain consumption in grams rather than servings. Koh-Banerjee and colleagues reported quintiles of median whole grain intakes from 3.0g/d to 43 g/d in the Health Professionals Follow-up Study (HPFS). They also showed that for every 40g /d increase in wholegrain intake, long term weight gain was reduced by 1.1kg. Jensen and colleagues (2004) found risk of coronary heart disease was reduced by 18% comparing highest and lower quintiles of intake in the same male cohort, and that each 20g/d increase in whole grain consumption was associated a 6% decrease in heart disease risk. Analysis of a subsample from the HPFS and NHS II reported median daily whole grain intakes of 7.4 to 43.8g/d; and 8.8 to 43.8 g/d, respectively (Jensen et al, 2006). The authors also observed lower levels of measures of glycemic control and homocysteine comparing the highest to lowest quintiles of whole grain intake. It is also important to note that Koh-Banerjee (2004) and Jensen (2004) also examined the health benefits of consuming only foods containing $\geq 51\%$ whole grain by weight; $\geq 25\%$ whole grain by weight; and foods that contained any amount of whole grain. The observed decrease in risk reduction was not significantly affected by the whole grain content of the foods consumed.

Approaches Used to Quantify the Amount Needed for Disease Reduction

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

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

Available studies show that risk reduction associated with consuming whole grain ranges from as little as 1 serving daily up to 3 servings per day. Comparatively, Koh-Banerjee and Jensen quantified whole grain intake and observed a benefit from a range of 42.7 to 43.8 g/d based on median intake, and 49.6 g/d based on mean intakes. Comparing the analyses of whole grain consumption only from

products that would qualify for the FDA Whole Grain Health Claim ($\geq 51\%$ whole grain by weight) to the analyses of whole grain from all foods did not change the associated benefits. This suggests the health benefits of whole grain are independent of the whole grain concentration of the food source (Jensen et al, 2004) when total intake of whole grain is comparable.

Current dietary guidance recommends the consumption of at least 3 servings (or ounce-equivalents) of whole grain each day. Review of the scientific literature on the health benefits of whole grain also supports consumption of 3 servings per day, or a range of 42.7 to 43.8 g/d or 49.6g based on mean intakes. The most frequently consumed grain-based food in the American diet is white bread (NHANES 99-02). Applying the rationale that the reference weight for a standard size slice of commercial bread (26 g) contains 16 g of grain (USDA Pyramid Servings Database), 3 servings of bread would provide 48 g of grain, or in essence 48 g of whole grain.

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

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

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

This AACC Intl. Task Force would like to go on record asking for the following labeling of all whole grains in order to help consumers decipher product labels. We recommend that manufacturers be encouraged to use the word 'whole grain' in the ingredient list when describing whole grains (but may use "whole wheat flour" in accordance with the standard of identity). Examples of descriptions that would lessen confusion include (but are not limited to) the following:

Current Common Label Designations	Recommended Clarification
Cornmeal	Whole grain cornmeal
Bulgur	Whole bulgur wheat
Oatmeal	Oatmeal (whole grain oats)
Graham flour	Whole wheat flour
Brown rice	Whole brown rice
Cracked wheat	Cracked whole wheat
Barley flakes	Whole grain barley flakes
Wheat berries	Whole wheat kernels
Farro (Faro)	Whole grain farro (ancient Italian grain)
Ground spelt	Whole grain spelt flour

Dietary Fiber as a Compliance Marker

AACC Intl. supports the use of dietary fiber as a marker for whole grain content as this is the only practical compliance marker available at this time. AACC Intl. recognizes the limitations of this marker and is looking for alternates, but these may not be available in the near future. We on

the Task Force appreciate that FDA has recently acknowledged whole grain is not a surrogate for fiber. The Task Force heartily agrees with this statement.

Background Data on Fiber and Whole Grains

Based on review of the scientific literature, our committee unanimously affirms that whole grain is not a surrogate for dietary fiber. While fiber is one of the health-promoting components of whole grains, there are many other health-promoting components in whole grains, as concluded by publications from scientific bodies of the U.S. government.

For example, in its 2005 report titled “Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients),” the Institute of Medicine stated that “Whole grain cereals are also sources of phytochemicals, such as phytate and phytoestrogens, which may independently impact CHD” (p. 369), and “There are many constituents of whole grains, in addition to dietary fiber, that may reduce the risk of CHD” (p. 387).

The 2005 Dietary Guidelines for Americans, prepared with input from FDA, reinforce this point when they establish separate recommendations for fiber and for whole grains, and when they refer to the “dietary fiber (also known as cereal fiber), vitamins, minerals, lignans, phytoestrogens, phenolic compounds, and phytic acid” present in whole grains. (p. 25).

The various health-promoting components of whole grains are further confirmed by the many research studies evaluating the relationship of whole grains to health outcomes. Many of these studies are detailed in the AACC International reference book “Whole Grain Foods in Health and Disease” (Exhibit A – submitted under separate cover) and in the enclosed reference list (Exhibit B).

At the same time the Task Force realizes the limitations of using dietary fiber as a compliance marker since the amount of dietary fiber naturally varies dramatically amongst the various grains, and even among subspecies within a grain type. The data in Table 1 illustrate the differences in dietary fiber content by grain type. Whole grains vary in fiber content from a low of about 3.5% (brown rice) to a high of about 17.3% (barley). Wheat, our most commonly-consumed grain, has one of the highest fiber contents, at about 12.2% fiber. These data reinforce that the dietary fiber content of whole wheat should not necessarily be used as the reference amount required for products based on other grain types.

Table 1: Dietary Fiber for Various Grain Types per 100g and RACC serving amounts

Dietary Fiber	Brown Rice	Whole Grain Corn Meal	Whole Oats	Whole Grain Wheat	Whole Grain Barley
100g	1.8g	7.3g	10.3g	12.2g	13.7
55g	0.99g	3.65g	5.67g	6.71g	7.53
30g	0.54g	2.19g	3.09g	3.66g	4.11

(Table from USDA data)

These fiber levels also suggest that, when consumed in serving sizes recommended by the Dietary Guidelines, whole grains virtually never provide an excellent source of fiber (5g of fiber), and may not even reach the “good source of fiber” level, as illustrated in Table 2 below. Clearly, whole grains do not equal fiber, just as fiber does not equal whole grains.

Table 2: Fiber Content of One Whole-Grain Ounce-Equivalent

Food Item	Amount in Household Measures	Dry Weight of whole grain or whole grain flour (gm)	Dietary Fiber (gm)
Bread, 100% whole-wheat, commercial	1 slice	16g	1.95g
Cereal, 100% whole grain, ready-to-eat	1 cup	28g	3.11g
Cereal, 100% whole grain, cooked	1/2 cup	27g	3.00g
Rice, brown, medium grain, cooked	1/2 cup	29g	1.02g
Macaroni, 100% whole wheat, cooked	1/2 cup	25g	3.05g
Popcorn, air-popped	3 cups	24g	3.48g

(Table derived from 2005 Dietary Guidelines for Americans, pg 54, Appendix A-2, Note 2, courtesy USDA.)

The AACC Intl. Expert Task Force on Bioactives in Whole Grains is defining a research platform to look for biomarkers in order to measure compliance for label claims. While some of these suggestions such as bound ferulate appear to be promising at least in grains such as wheat, much more research is needed before for these could be used to establish label compliance. A practical way to use ferulate and other potential phytochemicals as analytical markers for whole grain will require a number of years to develop. In the meantime, we stress that dietary fiber is currently the only viable option. In addition to the variability in fiber levels already discussed, dietary fiber can be easily added to foods making it difficult to distinguish the contribution of whole grain and non-whole grain ingredients to the total fiber content.

Exhibit B

Studies Referenced Above, on Dietarily Significant Amounts of Whole Grain

1. Fung TT, Hu FB, Pereira MA, Liu S, Stampfer MJ, Colditz GA, Willett WC. **Whole-grain intake and the risk of type 2 diabetes: a prospective study in men.** Am J Clin Nutr. 2002 Sep;76(3):535-40.
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12. Meyer KA, Kushi LH, Jacobs DR Jr, Slavin J, Sellers TA, Folsom AR. **Carbohydrates, dietary fiber, and incident type 2 diabetes in older women.** Am J Clin Nutr. 2000 Apr;71(4):921-30.
13. Steffen LM, Jacobs DR Jr, Stevens J, Shahar E, Carithers T, Folsom AR. **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.** Am J Clin Nutr. 2003 Sep;78(3):383-90.

Additional Studies Supporting the Health Benefits of Whole Grain

1. Good C, et al. ***The relationship between whole grain consumption and body mass index in adult men and women: data from the USDA's 1994-96 Continuing Survey of Food Intakes by Individuals, Pyramid Servings Data.*** FASEB J. 2004;18:A114.
2. Harnack L, Walters SH, Jacobs DR. ***Dietary intake and food sources of whole grains among US children and adolescents: data from the 1994-1996 Continuing Survey of Food Intakes by Individuals.*** J Am Diet Assoc. 2003;103:1015-1019.
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