

10841 S. Parker Road, Suite 105  
Parker, CO 80134  
Telephone: 303/840-8787  
Fax: 303/840-6877  
Web Site: www.wheatfoods.org  
E-Mail: wfc@wheatfoods.org

0744 '06 APR 27 A9:22



April 11, 2006

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

**RE: Docket No. 2006D-0066**

The Wheat Foods Council (WFC) is responding to the announcement in the Federal Register, vol. 71, No. 33, Friday February 17, 2006 regarding Draft Guidance for Industry and FDA staff: Whole Grains Label Statements: Availability.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 Wheat Foods Council is a non profit organization formed in 1972 to help increase public awareness of grains, complex carbohydrates and fiber as essential components of a healthy diet. The Council is supported voluntarily by wheat producers, millers, bakers and related industries.

Wheat Foods Council applauds the FDA for its clear statements regarding the nature and definition of whole grains. We support whole grain labeling that will encourage increased consumption of whole grains and help consumers recognize whole grain products in the marketplace. Whole grains have nutritive value from many vitamins, minerals and phytonutrients, in addition to fiber. The intent of the 2005 Dietary Guidelines for Americans and MyPyramid is to increase American's consumption of whole grains. Therefore, it is essential that the consumer be able to accurately identify these foods in the grocery store.

We are pleased at FDA's decision to use the AACC International's definition of whole grains and are fully supportive of their comments to FDA on this issue, as we were part of their task force.

While FDA has included a partial list of whole grains and makes no claims to it being comprehensive, there is mention of some of the unusual grains while

2006D-0066

C20

others are omitted. In our opinion, this could very well add to the confusion by the consumer on what is a whole grain rather than clarifying. WFC recommends adding to the list to make it as comprehensive as possible and adding an explanation of those grains that may or may not be whole grain, such as bulgur and specific corn products. In addition we recommend that manufacturers be encouraged to use the words "whole" or "whole grain" in the ingredient list when describing whole grains.

The 2005 Dietary Guidelines recommends a minimum of 48 grams per day of whole grains (as part of a reference 2,000 calorie intake). If the goal is to educate consumers, then we need to tell them how much whole grain is present in a serving of a specific product and how much they need in a day. This can be accomplished by defining and identifying good and excellent sources or other appropriate descriptive language, and/or by providing factual statements such as – one serving of \_\_\_ contains 10 grams of whole grains; 48 grams are recommended each day. The most calorie efficient way to consume the recommended 48 grams is in three 16-ounce servings; however, the ultimate goal is 48 grams so that informing consumers how many are in a particular product will go a long way in helping them to manage their intake. While whole grains have yet to be defined as a nutrient, a large body of evidence exists supporting the nutritive value of whole grains. The 2005 Dietary Guidelines provides such "authority" to define the nutritive value of whole grains, and thus to allow for creation of nutrient content descriptors for whole grain content to be used in food product labeling.

The criteria for the current authoritative statements approved by FDA for whole grains allows food such as pizza with 51% whole grain crust and appropriate other components that meet low or moderated fat; low saturated fat and cholesterol to make such a claim. However, the proposed guidance does not stating that there would need to be 100% whole grain or whole wheat. It is the belief of the Wheat Foods Council that this would discourage the food industry from doing what nutrition professionals and consumers are counting on them to do – incorporate whole grains into foods in creative and innovative ways that help Americans increase the amount of whole grains in their diet.

Recent studies quantifying whole grain intake 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 contribute to the observed health benefits of whole grain. We believe the draft FDA Guidance to label foods with grams of whole grain would be put into context and may be important information to provide to consumers.

**We recommend that, if a product label states "xx grams of whole grains" the phrase, "at least 48 grams are recommended daily" should be included to provide context.**

This approach allows consumers to make healthy choices, while avoiding labeling standards that are overly restrictive and that may exclude a substantial number of healthful foods which contain whole grains but do not meet a specific threshold.

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. Epidemiological studies show combined 25% and 50% whole grain products result in huge benefits to the consumer. A major study suggests that ***the health benefits of whole grain are independent of the whole grain concentration of the food source when the total intake of whole grain is comparable.*** (Jensen MK, Koh-Banerjee P, Hu FB, Franz M, Sampson L, Gronbaek M, Rimm EB. Intakes of whole grains, bran and germ and the risk of coronary heart disease in men. *Am. J Clin Nutr.* 2004 Dec;80(6):1492-9).

Many studies show that risk reduction from whole grains ranges from as **little as one serving daily** up to three servings. (Liu S, Stampfer MJ, Hu FB, Giovannucci E, Rimm E, Manson JE, Hennekens CH, Willett WC. Whole-grain consumption and risk of coronary heart disease: results from the Nurses' Health Study. *Am J Clin Nutr.* 1999 Sep;70(3):412-9. Liu S, Manson JE Stampfer MJ, Hu FB, Giovannucci E, Colditz GA, Hennekens CH, Willett WC. A prospective study of whole-grain intake and risk of type 2 diabetes mellitus in US women. *Am J Public Health.* 2000 Sep;90(9): 1409-15, and Liu S. Sesso HD, Willett WC et al, Is intake of breakfast cereals related to total and cause-specific mortality in men? *Am J Clin Nutr.* 2003;77:594-599.)

In addition, the Dietary Guidelines suggests that the consumer can combine products to get their 48 grams per day. If more foods include five grams of whole grain per serving and the guidance from FDA includes descriptive categories for those foods that contain whole grain but do not reach the level of 100% whole grain, the public would benefit. Without this labeling flexibility the incentive for reformulating and designing new products would all but disappear. WFC urges FDA to consider including this in the guidance.

The Wheat Foods Council recommends that FDA provide sufficient flexibility for food labels to provide useful information for consumers to achieve dietary recommendations for whole grains from the 2005 Dietary Guidelines and MyPyramid. Confusion exists even among health professionals, let alone consumers, as to the difference between fiber content and whole grain content.

Effective and accurate food label information will support sustained nutrition education efforts from professional organizations, government entities and the private sector to promote consumption of whole grains.

Thank you for your consideration of this matter.

Sincerely,

A handwritten signature in black ink, reading "Marcia Scheideman". The signature is written in a cursive style with a large, looping initial "M".

Marcia Scheideman, MS, RD  
President