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Proposed Descriptive Claims for Whole Grain
21 C.F.R. Part 101 Subpart F

§ 101.9X Descriptive Claims for Whole Grains

(a) **General Requirements.** The terms defined in this section may be used on the label or in labeling of a food in conformity with the provisions of this section. The requirements of the section pertain to any use of the term whole grain as described in paragraph (b) in combination with the claims described in paragraph (c) to refer, expressly or implicitly, to the level of whole grain in a food on labels or labeling.

(b) **Whole grain.** Whole grain is a substance that includes all edible parts of the grain including, the bran, germ and endosperm. When used as a component of a food, all three edible parts of the grain must be present in the same proportion either naturally or through technological processes. Food ingredients that may be considered whole grains are amaranth, barley, buckwheat, bulgur, corn, oats, rice, rye and wheat.

(c) **Whole Grain Claims.** (1) The terms "high," "rich in," or "excellent source" may be used on the label and in the labeling of foods provided that the food contain 16 grams (g) or more of whole grain per serving size declared on the package.

(2) The terms "good source," "contains," or "provides" may be used on the label and in the labeling of foods provided that the food contains 8 g to 15 g of whole grain per serving size declared on the package.

(3) The term "made with" may be used on the label and labeling of foods provided that the food contains at least 8 g of whole grain per serving size declared on the package.

(d) **Specific Requirements.** (1) FDA will determine the amount of whole grain in a product declaring the claims identified in paragraph (c) by multiplying the fiber content of the food ingredient that comprises the whole grain component of the product with the amount of whole grain associated with the claim declared on the label or in the labeling. Fiber contents of the food ingredients will be based on the U.S. Department of Agriculture Nutrient Database.

(2) If the product contains more than one food ingredient that comprises the whole grain component of the product, FDA will use 11.1 g fiber/100 g as the representative fiber content of the whole grain blend. The same formula of the fiber content multiplied by the amount of whole grain associated with the claim will be used to determine whether the product complies with the declared claim.

(3) Nothing in this paragraph (d) will prevent the manufacturer from demonstrating through other information and the Agency from considering such

information that proves that the product contains the requisite whole grain levels required by the claim.

(e) *Misbranding*. Uses of whole grain claims not subject to this regulation will be governed by the provision of 403(a) of the Federal Food, Drug, and Cosmetic Act.