

Current FDA Guidance on Whole Grain Labeling

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This presentation will present the U.S. Food and Drug Administration's (FDA's) current thinking on how to label whole grain foods and what foods are considered whole grain. The presentation will also discuss the agency's draft guidance and provide examples to assist manufacturers in labeling their products about the presence of whole grain ingredients.

The FDA published a draft guidance for industry and FDA staff entitled "Whole Grain Label Statements" on February 17, 2006, which:

- Represents the FDA's current thinking
- Doesn't operate to bind the FDA or the public
- Can use alternative approaches if satisfy applicable statutes and regulations

What Are Whole Grains?

Cereal grains that 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, should be considered a whole grain food.

- Whole grains may include amaranth, barley, buckwheat, bulgur, corn (including popcorn), millet, quinoa, rice, rye, oats, sorghum, teff, triticale, wheat, and wild rice.
- Soybeans, chickpeas, oilseeds, and roots are not whole grains. Corn flour or corn meal should include the pericarp as well as other essential fractions (germ, endosperm, and seed coat) as a whole grain corn.
- Pearled barley is not a whole grain.
- Rolled oats are whole grain as long as they contain all of the bran, germ, and endosperm.

What Does the Term "Whole Grain" Mean on a Label?

Depending on the context in which a "whole grain" state-

ment appears on the label, it could be construed as meaning that the product is "100% whole grain." It is recommended that bagels labeled as whole grain or whole wheat only be labeled as such when they are made entirely from whole grain flours or whole wheat flour, respectively.

Products labeled with 100% whole grain should not contain grain ingredients other than what the agency considers to be whole grains.

FDA Draft Guidance on Label Statements

Manufacturers can make factual statements about the amount of whole grains on the label of their products (e.g., 100% whole grain under Title 21 Code of Federal Regulations section 102.5(b), 10 g of whole grain per serving) provided that the statements are not false or misleading (under section 403(a) of Federal FD&C Act) and do not imply a particular level of the ingredient (i.e., "high" or "excellent source").

The specific name of the whole grain (e.g., brown rice) can be used for label statements made under Title 21 Code of Federal Regulations section 102.5(b) as long as the statements are truthful and not misleading.

Permitted label statements include factual statements such as:

- 10 grams of whole grains/whole wheat per serving
- 1/2 ounce of whole grains/brown rice per serving
- 100% whole grain oatmeal

Health Claim

Manufacturers may use health claims relating whole grains with reduced risk of coronary heart disease and certain cancers on products label for qualifying foods based on a FDAMA notification.

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