

Guidance for Industry and FDA Staff

Whole Grain Label Statements

Draft Guidance

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**U.S. Department of Health and Human Services
Food and Drug Administration**

[February 2006]

*Contains Nonbinding Recommendations
Draft – Not for Implementation*

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*Additional copies are available from:
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This draft guidance, when finalized, will represent the Food and Drug Administration’s (FDA’s) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended for the regulated food industry and FDA personnel. The purpose of this guidance is to provide guidance to industry about what the agency considers to be "whole grain" and to assist manufacturers in labeling their products.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Through the years, the Federal Government has worked to provide consistent and scientifically sound recommendations to consumers about healthy eating patterns and wise food choices. Such advice originated with the “Basic Four” and has progressed through today’s “Dietary Guidelines for Americans” (developed jointly by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (USDA)). “Dietary Guidelines for Americans, 2005” (2005 DG) recommends that Americans, among other things, “consume 3 or more ounce-equivalents of whole grain products per day, with the rest of the recommended grains coming from enriched or whole-grain products” and that “in general at least half the grains should come from whole grains” (Ref. 1).

Manufacturers can make factual statements about whole grains on the label of their products such as "100% whole grain" (as percentage labeling under 21 CFR 102.5(b)) or "10 grams of whole grains" (21 CFR 101.13(i) (3)) provided that the statements are not false or misleading under section 403(a) of the Federal Food, Drug,

¹ This draft guidance has been prepared by the Food Labeling and Standards Staff; Office of Nutritional Products, Labeling, and Dietary Supplements; Center for Food Safety and Applied Nutrition at the Food and Drug Administration.

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and Cosmetic Act (the Act) and do not imply a particular level of the ingredient, i.e., "high" or "excellent source." In addition, manufacturers may use health claims relating whole grains with a reduced risk of coronary heart disease and certain cancers on their product labels for qualifying foods based on notifications FDA received under section 403(r)(3)(C) of the Act (21 U.S.C. 343 (r)(3)(C)) (health claims based on an authoritative statement of a scientific body) (see <http://www.cfsan.fda.gov/~dms/labfdama.html>). To assist manufacturers in labeling their products in accordance with the Act, the agency has reviewed various industry and scientific definitions of "whole grains" and developed the following questions and answers to provide guidance to industry about what the agency considers to be "whole grain."

III. DEFINITION—QUESTIONS AND ANSWERS

1. **Question:** What factors should be considered in determining whether a food is a whole grain?

Answer: 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.

2. **Question:** What are some examples of cereal grains?

Answer: Cereal grains may include amaranth, barley, buckwheat, bulgur, corn (including popcorn), millet, quinoa, rice, rye, oats, sorghum, teff, triticale, wheat, and wild rice.

3. **Question:** Should soybeans and chickpeas be considered whole grains?

Answer: Soybeans and chickpeas should not be considered whole grains, but should be considered legumes. Products derived from legumes, oilseeds (sunflower seeds), and roots (e.g., arrowroot) should not be considered whole grains.

4. **Question:** Should a corn flour or corn meal made from corn grain to which the pericarp has been removed be considered whole grain?

Answer: The four principal parts of a mature corn kernel consist of the hull or bran (pericarp and seed coat), germ, endosperm, and the tip cap (Ref. 2). The tip cap, the attachment point of the cob, may or may not stay with the kernel during handling, and, thus, is not considered an integral part of the kernel or caryopsis. However, the bran, germ and endosperm are integral parts of the kernel and should be present in the relative proportions as found in the kernel to be considered "whole grain." Therefore, for corn flour or corn meal to be "whole grain" it should include the pericarp as well as the other essential fractions.

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We note that there are standards of identity for various types of corn flour and corn meal in 21 CFR Part 137 (i.e., § 137.211, white corn flour; § 137.215, yellow corn flour; § 137.250, white corn meal; § 137.255, bolted white corn meal; § 137.260, enriched corn meals; § 137.265, degerminated white corn meal; § 137.270, self-rising white corn meal; § 137.275, yellow corn meal; § 137.280, bolted yellow corn meal; § 137.285, degerminated yellow corn meal; and § 137.290, self-rising yellow corn meal). Degerminated and bolted corn meals should not be considered whole grain products because germ or bran has been removed during processing. Because the rest of the meal standards allow removal of some of the hull, these also should not be considered whole grain products.

5. **Question:** Barley has a particularly tough hull and is often pearled to make it easier to cook and digest. Can the hull and perhaps a small amount of the bran attached to the hull be removed from barley in the pearling process and it still be considered a whole grain?

Answer: Most of the barley that is used for food production in the U.S. is of a type in which the kernels are covered with a very tough inedible hull. This outer hull (which covers the bran layer) must be removed before the kernel can be used for human food. The hull on many varieties of barley is strongly attached to the pericarp. Thus, barley is difficult to dehull and generally is pearled. The pearling process abrades away the outer surfaces of the grain with an abrasive surface and removes some of the bran from the barley.

In general, the barley that is used for human food in the U.S. is pearled. Barley that is pearled should not be considered a whole grain because some of the bran layer has been removed. Dehulled barley should be considered a whole grain because only the tough inedible hull or outer covering has been removed, but the bran layer is left intact.

6. **Question:** Should rolled oats be considered a whole grain?

Answer: In the U.S. most oats are flattened to produce rolled oats, or steamed and flattened to create “quick oats.” Rolled oats and “quick oats” processed simply by flattening and/or steaming should be considered whole grains because they contain all of the bran, germ, and endosperm of whole oats.

7. **Question:** Does the term “whole grain” mean the same as “100 percent whole grain”? If a product is labeled as “whole wheat bagel” or “whole wheat pizza,” how much whole wheat should it contain? What is graham flour?

Answer: FDA has not defined any claims concerning the grain content of foods. However, the agency has established standards of identity for various types of cereal flours and related products in 21 CFR Part 137, including a standard of identity for “whole wheat flour” (§ 137.200) and “whole durum flour”

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(§ 137.225). Graham flour is an alternative name for whole wheat flour (§ 137.200).

Depending on the context in which a “whole grain” statement appears on the label, it could be construed as meaning that the product is “100 percent whole grain.” We recommend that products labeled with “100 percent whole grain” not contain grain ingredients other than those the agency considers to be whole grains. Consumers should be able to look at the ingredient statement to determine whether the predominant or first ingredient listed is a whole grain. We note that wheat flour should not be labeled as a whole grain flour because wheat flour is a synonym of flour (§ 137.105), and thus, the bran and germ have been removed. However, whole wheat flour (§ 137.200) should be considered a whole grain flour because it contains all the parts of the grain, i.e., the bran, endosperm, and germ. We recommend that pizza that is labeled “whole grain” or “whole wheat” only be labeled as such when the flour ingredient in the crust is made entirely from whole grain flours or whole wheat flour, respectively. Similarly, we recommend that bagels, labeled as “whole grain” or “whole wheat” only be labeled as such when bagels are made entirely from whole grain flours or whole wheat flour, respectively.

8. **Question:** What is durum wheat? Is it 100 percent whole grain? What products are made from durum wheat?

Answer: Durum wheat is a type of wheat that has a high protein content and the flour has a yellow color. It is typically used for semolina and pastas. Durum flour should not be considered a whole grain flour because the germ and bran have been removed (21 CFR 137.220). However, whole durum flour (21 CFR 137.225) should be considered a whole grain flour because the flour contains all the parts of the grain, i.e., the bran, endosperm, and germ. We recommend that products labeled with “100 percent durum wheat” statements be made entirely with durum flour and products labeled “whole grain” be made entirely from whole durum flour.

9. **Question:** Are there standards of identity for products made from whole grains?

Answer: There are no standards of identity for whole grain products per se. However, there are standards of identity for whole wheat bread, rolls, and buns (21 CFR 136.180) and whole wheat macaroni products (21 CFR 139.138) which are made from whole wheat flours. For bread, rolls, and buns, the dough is made from whole wheat flour, brominated whole wheat flour, or a combination of these and no other type of flour is used. Whole wheat macaroni products are made from whole wheat flour, whole durum wheat flour, or both.

10. **Question:** What types of label statements about whole grains are currently permitted to be made on food products?

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Answer: Manufacturers can make factual statements about whole grains on the label of their products, such as “10 grams of whole grains,” “_ ounce of whole grains,” (21 CFR 101.13(i)(3)) and “100% whole grain oatmeal” (as percentage labeling under 21 CFR 102.5(b)), provided that the statements are not false or misleading under section 403(a) of the Act and do not imply a particular level of the ingredient, i.e., “high” or “excellent source.”

In addition, labels may bear a health claim based on an authoritative statement of a scientific body relating whole grains with a reduced risk of heart disease and certain cancers if the food meets the qualifications of one of the notifications submitted under section 403(r)(3)(C) of the Act (see <http://www.cfsan.fda.gov/~dms/labfdama.html>).

11. **Question:** Can the name of the particular whole grain be substituted for the term “whole grain” in label statements? For example, could the statement “100% brown rice” replace the statement “100% whole grains” or “1 ounce whole wheat” replace “1 ounce whole grain?”

Answer: The specific name of the whole grain (e.g., brown rice) can be used for label statements made under 21 CFR 102.5(b) or 21 CFR 101.13(i) (3) as long as the statement is truthful and not misleading. However, “whole grains” is the substance of the health claims established under section 403(r) (3)(C) of the Act and the name of a particular whole grain can not be substituted for the term “whole grain foods” in the health claims.

IV. REFERENCES

The following reference have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Department of Health and Human Services and U.S. Department of Agriculture, “Dietary Guidelines for Americans, 2005,” www.healthierus.gov/dietaryguidelines, 2005.
2. Hosene, R. Carl, “*Corn*,” “Principles of Cereal Science and Technology,” St. Paul, MN, 1986.