

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. 2006D-0066]

**Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements; Availability**
**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry and FDA Staff: Whole Grain Label Statements." The draft guidance is intended to provide guidance to industry about what the agency considers to be "whole grain" and to assist manufacturers in labeling their products.

**DATES:** Submit written or electronic comments concerning the draft guidance by April 18, 2006, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document to the Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance, to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Shellee Anderson, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1491, e-mail: [shellee.anderson@fda.hhs.gov](mailto:shellee.anderson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**
**I. 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). "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 may 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, and Cosmetic Act (the act) (21 U.S.C. 343(a)) 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 to 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, the agency has reviewed various industry and scientific definitions of "whole grains" and developed guidance to industry about what the agency considers to be "whole grain."

The agency has adopted good guidance practices (GFPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance is being issued as a Level 1 guidance document consistent with the GFPs. The draft guidance represents the agency's current thinking on the 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 may use an alternative approach if such approach satisfies the requirements of applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**).

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. If you base your comments on scientific evidence or data, please submit copies of the specific information along with your comments. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at: <http://www.cfsan.fda.gov/guidance.html>.

**IV. References**

The following reference has 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," <http://www.healthierus.gov/dietaryguidelines>, 2005.

Dated: February 14, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**National Institutes of Health**
**Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.