information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, in the **Federal Register** of April 29, 2010 (75 FR 22599), FDA published a notice of availability of the draft guidance document providing a 60-day public comment period on the proposed collection of information provisions.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry and FDA Staff: FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act.

Description: Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining the Agency's views about the classification and regulatory requirements that may be applicable to your particular device. Section 513(g) provides that within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device.

Section 513(g) of the FD&C Act provides a means for obtaining FDA's views about the classification and the regulatory requirements that may be applicable to a particular device. The purpose of this draft guidance is to establish procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA's responses to 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act. Additionally, the FD&C Act, as amended by the FDA Amendments Act of 2007 (Pub. L. 110–85), requires FDA to collect user fees for 513(g) requests for information.

In the **Federal Register** of April 29, 2010, FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act 513(g)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Center for Devices and Radiological Health (CDRH)	110	1	110	12	1,320
Center for Biologics Evaluation and Research (CBER)	4	1	4	12	48
Total					1,368

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are mostly device manufacturers; however, anyone may submit a 513(g) request for information. The total number of annual responses is based on the average number of 513(g) requests received each year by the Agency. FDA based its estimates on the number of 513(g) requests for information received by both CDRH and CBER from 2007 to 2009.

Dated: May 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13058 Filed 5–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0320]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study entitled: "Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages."

DATES: Submit either electronic or written comments on the collection of information by July 25, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the

docket number found in brackets in the heading of this document. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

I. Background

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages, 21 U.S.C. 393(d)(2)(C)—(OMB Control Number 0910—New)

The Nutrition Labeling and Education Act (NLEA), which amended the Food, Drug and Cosmetic Act, requires most foods to bear nutrition labeling (*i.e.,* the Nutrition Facts), and requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements. There are three different types of claims (health claims, nutrient content claims, and structure/function claims) that the food industry can voluntarily use on food labels. Although they are regulated differently, they all must be truthful and not misleading (Ref. 1).

In the past 30 years, whole-grain consumption has been greatly promoted by government agencies and scientific communities as an important part of a healthy diet (Refs. 2 and 3). For example, the newly-released "Dietary Guidelines for Americans 2010" recommends Americans eat fewer refined grains, and consume more nutrient-dense whole grains instead (Ref. 4). At the same time, whole grain labeling statements, such as "Made With Whole Grain," on food products have also become more prevalent in recent years (Ref. 5). Given the variety of whole-grain statements on food products and the importance of whole grains in maintaining a healthy diet, it is important for policy makers to gain a better understanding of how consumers interpret these statements.

Several studies indicate that consumers may have difficulties in understanding the meaning of whole grains or recognizing whole-grain foods (Refs. 6 to 8). Research also suggests consumer product perceptions and purchase decisions can be influenced by labeling statements and different labeling statements may have different influences (Refs. 9 and 10). The majority of existing studies focus on whole grain intake or the relationships between whole grain and disease prevention. There is a lack of systematic investigation of consumers' understanding of different whole-grain labeling statements. We are aware of at least one existing study related to the statements (Ref. 11). However, the study did not compare consumer reactions to various whole-grain statements. Therefore, the FDA, as part of its effort to promote public health, plans to use the proposed study to explore and compare consumer responses to food labels that use whole grains labeling statements.

Specifically, the study plans to examine: (1) Consumer judgments about a food product including its nutritional attributes, overall healthiness, and health benefits; (2) consumer judgments about a label in terms of its credibility in conveying the product's nutritional attributes and its helpfulness in making product purchasing decisions; (3) consumer perceptions about differences between different statements, such as "Made with Whole Grain," "Contains Whole Grain," and "Whole Grain;" (4) consumer extrapolation of whole grain statements beyond the scope of the statements themselves (*i.e.,* halo effects); and (5) how whole grain statements influence consumer use of the Nutrition Facts.

The proposed collection of information is a controlled randomized experimental study. The study will use a 15-minute Web-based survey to collect information from 2,700 English-speaking adult members of an online consumer panel maintained by a contractor. The study will aim to produce a sample that reflects the U.S. Census on gender, education, age, and ethnicity/race.

The study will randomly assign each participant to view two label images from a set of food labels that will be created for the study and systematically varied in the: (1) Whole grain labeling statements; (2) nutritional profiles (differing by the amount of fiber); (3) ingredient lists (differing by the ranking order of whole grain wheat on the list); and (4) featured product (*e.g.,* bread, cereal, and breakfast bars). With regard to claims, the study will focus on examples of whole grain statements that can be found on food packages. All label images will be mock-ups resembling food labels that may be found in the marketplace. Images will show product identity (*e.g.,* bread), but not any real or fictitious brand name. The study will provide interested participants access to the Nutrition Facts, but not together with a product image.

The survey will ask its participants to view two label images one at a time and answer questions about their perceptions and reactions related to each of the products and labels. Product perceptions (*e.g.,* healthiness, potential health benefits, levels of whole grains and fiber amount) and label perceptions (*e.g.,* helpfulness and credibility) will constitute the measures of responses in the experiment. To help understand the data, the survey will also collect information about participants' backgrounds, such as consumption, purchase history, perception, and familiarity with a category of food; awareness and knowledge of nutrients and substances; health literacy; and health status and demographic characteristics.

The study is part of the agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. Results of the study will be used primarily to enhance the agency's understanding of how whole grains claims and other related

labeling statements on food packages may affect how consumers perceive a product or a label, which may in turn affect their dietary choices. Results of the study will not be used to develop population estimates.

To help design and refine the questionnaire, FDA plans to conduct cognitive interviews by screening 72 panelists in order to obtain 9 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hour) and each cognitive interview is expected to take one hour. The total for cognitive interview activities is 15 hours (6 hours + 9 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1,600 invitations, each taking 2 minutes (0.033 hour), will need to be sent to panelists to have 200 of them complete a 15-minute (0.25 hour) pretest. The total for the pretest activities is 103 hours (53 hours + 50 hours). For the survey, we estimate that 21,600 invitations, each taking 2 minutes (0.033 hour) to complete, will need to be sent to the consumer panel to have 2,700 of its members complete a 15-minute (0.25 hour) questionnaire. The total for the survey activities is 1,388 hours (713 hours + 675 hours). Thus, the total estimated burden is 1,506 hours. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Cognitive interview screener	72	1	72	5/60	6
Cognitive interview	9	1	9	1	9
Pretest invitation	1,600	1	1,600	2/60	53
Pretest	200	1	200	15/60	50
Survey invitation	21,600	1	21,600	2/60	713
Survey	2,700	1	2,700	15/60	675
Total					1,506

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

II. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, under Docket No. FDA–2011–N–0320 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified all Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. U.S. Food and Drug Administration, "Claims That Can Be Made for Conventional Foods and Dietary Supplements," September 2003, available at *http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm111447.htm.*
2. Cleveland, L. E., A.J. Moshfegh, A.M. Albertson, and J.D. Goldman, "Dietary intake of whole grains," *Journal of the American College of Nutrition,* 19, 331S–338S, 2000.
3. Kantor, L. S., J.N. Variyam, J.E. Allshouse, J.J. Putnam, and B.H. Lin, "Choose a variety of grains daily, especially whole grains: A challenge for consumers," *Journal of Nutrition,* 131, 473S–486S, 2001.
4. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Executive Summary of Dietary Guidelines for Americans, 2010," January 2011, available at *http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/ExecSumm.pdf.*
5. *Supermarket News,* "Report: Whole Grains Gain Momentum," September 2010, available at *http://supermarketnews.com/news/whole_grains_0917/#.*
6. Arvola, A., L.Lähteenmäki, M. Dean, M. Vassallo, M. Winkelmann, E. Claupein, A. Saba, and R. Shepherd, "Consumers' beliefs about whole and refined grain products in the UK, Italy and Finland," *Journal of Cereal Science,* 46, 197–206, 2007.
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10. Willis, Josephine M., and K.G. Grunert, "A Review of Research on Consumer Response to Nutrition Information on Food Packaging," 2007.
11. Kellogg Co. "A Survey of Consumers' Whole Grain & Fiber Consumption Behaviors, and the Perception of Whole Grain Foods as a Source of Dietary Fiber," 2010. FDA Docket No. 2006–D–0298, July 2010, available at *http://www.regulations.gov/#!documentDetail;D=FDA-2006-D-0298-0016.*

Dated: May 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13060 Filed 5–25–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0366]

Food and Drug Administration Food Safety Modernization Act: Focus on Inspections and Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "FDA Food Safety Modernization Act: Focus on Inspections and Compliance." The purpose of the public meeting is to provide interested persons an opportunity to discuss implementation of inspections and compliance under the recently enacted FDA Food Safety Modernization Act (FSMA). More specifically, the public will have an opportunity to provide information and share views that will inform FDA's