Kimberly Lane,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

The meeting scheduled to convene on February 28–29, 2012 was published in the **Federal Register** on February 16, 2012, Volume 77, Number 32, Pages 9254–9255. This notice was put on display for 12 days in advance of the meeting instead of the 15 calendar days required in accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), and pursuant to the requirements of 42 CFR 83.15(a).

CONTACT PERSON FOR MORE INFORMATION: Theodore Katz, M.P.A., Executive Secretary, NIOSH, CDC, 1600 Clifton Road, NE., MS E–20, Atlanta, Georgia 30333, Telephone: (513) 533–6800, toll free: 1–800–CDC–INFO, email: *dcas@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 17, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–4569 Filed 2–24–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0320]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 28, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages.'' Please also include the FDA docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages—(OMB Control Number 0910–New)

I. Background

The Nutrition Labeling and Education Act, which amended the Federal 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, 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-grain 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 labeling statement in terms of its credibility, helpfulness, and other attributes; (3) consumer interpretations of different terms and statements, such as ''Made with Whole Grain'', ''Multi-Grain'', and ''100% Whole Wheat''; (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 one label image from a set of food labels that will be created for the study and systematically varied in the (1) whole grain labeling statement; (2) featured product (e.g., bread, salty snacks, and breakfast bars); (3) access to the Nutrition Facts label; and (4) nutritional profile (differing by the amount of fiber and the ranking order of whole grain products on the ingredient list). 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 half of the participants access to the Nutrition Facts but not together with a product image (i.e., these participants can look at the Nutrition Facts if they choose to). The study will show the other half of the respondents a label in which the Nutrition Facts is located next to the product image.

The survey will ask its participants to view label images and answer questions about their perceptions and reactions related to the product and claim. 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 response in the experiment. To help understand the data, the survey will also collect information about participants' backgrounds, such as consumption and purchase patterns, awareness and knowledge of nutrients and substances, 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.

In the **Federal Register** of May 26, 2011 (76 FR 30725), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received eight letters in response to the notice, each containing multiple comments. Several comments were generally supportive of FDA's study. Additional comments were outside the scope of the four collection of information topics on which the notice solicits comments and will not be discussed in this document. The comments on the four collection of information topics, and the Agency's responses, are discussed in the following paragraphs.

(Comment 1) One comment questioned the necessity of the study given FDA's many pressing responsibilities. The comment suggested that the ''Dietary Guidelines for Americans 2005'' and the prevalence of Whole Grain Stamps on products have increased consumer ability to understand the benefits of whole grains and to find and purchase them in stores.

(Response) FDA disagrees with this comment. Research suggests that although consumers may be aware of the benefits of whole grain foods, they still have difficulties in understanding the meaning of whole grains or recognizing whole grain foods (Refs. 6 through 8). Given the multitude of whole grain statements appearing in the marketplace and the importance of whole grains in maintaining a healthy diet, there is a genuine need for systematic investigation of how consumers interpret various whole-grain statements.

(Comment 2) Several comments suggested improvements to the proposed survey instrument. One comment questioned whether the terms ''healthiness'' and ''nutritional qualities'' should be equated to one another as in a proposed response item ''healthiness or nutritional qualities.'' A few comments noted that the scales of the ranking questions need to be revised from a four or six point scale to a five point scale with a ''neutral position'' (e.g., neither agree nor disagree). Several comments questioned whether a ''don't know'' choice should be included or omitted in several places. One comment suggested that the section on general knowledge of whole grains should be asked before questions on specific labels. One comment stated that the questions on evaluating the trustworthiness and helpfulness of the whole grain statement may be biased or leading because all the negative terms are placed on the left-hand side of the scale. Another comment stated that the perceptions of the claim statement may be confounded by product cues such as color and graphics.

(Response) FDA has carefully reviewed the survey instrument and has incorporated all necessary clarifications and improvements in response to the comments. In terms of the perceived connection between ''healthiness'' and ''nutritional qualities,'' FDA found in previous cognitive testing that some respondents understood nutritional qualities as an element of healthiness and equated the two concepts, as in ''healthiness or nutritional qualities.'' The testing also found that this expression performed best in respondent comprehension and in conveying the intent of the item, which is the nutritional aspect of health. Therefore, we have decided to retain the expression ''healthiness or nutritional qualities.'' Regarding inclusion of a ''neutral'' (neither agree nor disagree) response in the rating scales, research (e.g., Ref. 12) has suggested that such a response can be interpreted as a ''don't know'' response by some respondents. Therefore, we have kept the six point rating scale and added a ''don't know'' option. Questions whose response options purposefully omit a ''don't know'' option will be further evaluated in the cognitive interviews to confirm that participants are able to select one of the provided choices. Regarding the order of the general knowledge and label response sections, we disagree with the suggestion and believe the suggested change would create more biases than the current order. We also disagree that claim perceptions may be biased because negative terms are placed on the left-hand side of the scale. Existing research has not produced consensus about whether placing negative or positive terms at the beginning of a scale is more likely to cause biases. More importantly, because this is an experimental study that employs random assignment, bias is irrelevant as we are mainly interested in quantitative differences in dependent measures between tested stimuli (e.g., claims). We agree that product cues may make it difficult to isolate the impact of whole grain claims. For this reason, the study has created mock-up labels that do not include real or fictitious brand names and only resemble, but are not identical to, real packages. Moreover, the study will compare responses to labels that differ only in the presence or absence of a claim, and in the claim language, but not in any other respect.

(Comment 3) One comment suggested that FDA should clearly define in the

study concepts such as ''whole grains'', ''foods made from whole grains'', and ''whole grain food'' when asking about whole grain consumption.

(Response) We disagree with this suggestion. How consumers interpret these labeling statements is the core question that FDA is interested in answering and clear definitions would defeat this purpose. In the modified version of our questionnaire, we have provided specific examples of whole grain products (such as cereal or bread, pasta that are made with whole grains) when we ask participants about their whole grain consumption patterns.

(Comment 4) One comment proposed revising a question in the survey that is intended to assess potential consumer confusion about the meaning of organic versus whole grain. The question we proposed asked participants to judge the likelihood that a product is organic based on the information shown on the experimental label stimuli.

(Response) The question FDA originally proposed (how likely a product shown in the survey is organic) has been removed from the revised questionnaire. Instead, we have added a new question that asks whether respondents think the statement ''All whole grain foods are organic'' is true or false.

(Comment 5) One comment stated that consumers do not understand ''ounce-equivalents'' when trying to answer the whole grain consumption questions. The comment suggested using grams or servings as a measurement of whole grain, or other basic descriptions of amounts as included in the ''Dietary Guidelines for Americans'' or MyPlate (e.g., half of the grains you consume, half of a plate).

(Response) We agree that consumers are probably more familiar with measurements expressed in servings or grams than with measurements expressed in ounce-equivalents and have replaced ounce-equivalents with servings or grams in the study. Also, we have removed the question about whether consumers are aware of the recommended amount of whole grains they should consume according to the Dietary Guidelines for Americans because respondents may not know details in the ''Dietary Guidelines for Americans'' or MyPlate.

(Comment 6) One comment suggested that FDA should incorporate the three standards listed in the ''Dietary Guidelines for Americans 2010'' (''look for 100% whole grain foods''; ''look for products using the FDA whole grain health claim''; ''look for products with at least 8 grams of whole grain'') into the study to see whether consumers can use them to seek out whole grains.

(Response) We agree that this information is useful and have included these standards in the study. We will examine how well respondents understand them and whether they can evaluate the amount of whole grain in a certain food based on the claim on the front of the food package and the Nutrition Facts and the ingredient list on the back.

(Comment 7) One comment suggested that FDA add a variety of grains and more non-wheat-based foods (e.g., brown rice, oatmeal, and popcorn) to see if consumers understand these are whole grain foods. The same comment also suggested FDA include more foods lower in overall grain content than the three planned (bread, cereal, breakfast bars), as these are likely to be high in grain content.

(Response) We agree with the comment and have included bread, salty snacks (instead of cereal), and breakfast bars in the study.

(Comment 8) One comment suggested that FDA add more questions on participants' consumption, purchases of the food categories studied, and health and nutrition attitude questions. The comment also suggested that FDA explore consumers' understanding of whole grains relative to consumers' understanding of other aspects of a healthy diet, such as consumption of leafy green vegetables or legumes. The comment stated that the information can help reveal whether consumer knowledge about dietary practices other than whole grain consumption might require greater Agency resources and attention.

(Response) We have added questions on participants' consumption and purchase of the food categories that will be studied (bread, breakfast bars, and salty snacks). Due to resource limitations, we will not be able to ask additional questions about participants' understanding of other aspects of a healthy diet or expand the study to include a larger group of foods.

(Comment 9) One comment suggested that, in addition to testing two nutritional profiles for a given product (one high in fiber amount and one low in fiber amount), the study should include at least one product that provides a good source of fiber.

(Response) We agree that the suggested addition will increase our understanding of consumer reactions to products with various fiber contents. We have included three types of foods: Bread, breakfast bars, and salty snacks (instead of cereal), each with two nutritional profiles (one high in fiber amount and one low in fiber amount) in the study. Bread usually provides a good source of fiber.

(Comment 10) One comment suggested that, because the focus of the proposed research is on interpretation of whole grain label statements, the data analysis should treat the label statements as fixed effects and the product categories and nutrition profiles as random effects.

(Response) We will consider the need and appropriateness of the suggested analytic approach during data analysis.

(Comment 11) Several comments urged FDA to provide graphics and revised instruments in the 30-day notice for public comment.

(Response) We agree and have included these materials in the information collection request.

(Comment 12) One comment encouraged FDA to revise its draft guidance to provide clear guidance to industry as to the types of claims that may be made about whole grains and also to limit whole grain claims to foods that provide at least a good source of fiber (10% Daily Value) for foods with a mid to large size Reference Amount Customarily Consumed (RACC), such as those associated with ready-to-eat cereals.

(Response) The comment is outside of the scope of the proposed collection of information described in the 60-day notice and therefore is not addressed here. Nonetheless, the comment has been forwarded to the docket for the whole grain draft guidance.

FDA estimates the burden of this collection of information as follows (Table 1). FDA plans to conduct cognitive interviews by screening 72 panelists in order to obtain 9 individuals for cognitive interviews. Each screening is expected to take 5 minutes (0.083 hour), and each cognitive interview is expected to take 1 hour. The total for cognitive interview activities is 15 hours (6 hours + 9 hours). Subsequently, we plan to screen 1,152 individuals for pretest, each taking 2 minutes (0.033 hours), in order to have 576 of them complete a 15-minute (0.25 hours) pretest. The 576 target responses are 376 more than the 200 target responses described in the 60-day notice. The change is because we increased the number of our experimental conditions from 156 to 288, and we wanted to ensure two responses per experimental condition (288 * 2). Thus, the total for the pretest activities is 182 hours (38 hours + 144 hours). For the survey, we estimate that 5,400 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer

panel to have 2,700 of them complete a 15-minute (0.25 hours) questionnaire. The total for the survey activities is 855 hours (180 hours + 675 hours). Therefore, the total estimated burden is 1,052 hours. This estimate is 454 hours lower than the 1,506 hours described in the 60-day notice and reflects 15 fewer hours for pretest invitation, 533 fewer hours for survey invitation, and 94 more hours for the pretest, respectively. Recent experience by our contractor suggests that the Agency will not need to send as many invitations as originally estimated to achieve its target sample sizes in pretest and survey. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener	72	1	72	0.083 (5 minutes)	6
Cognitive interview	9	1	9	1 hour	9
Pretest invitation	1,152	1	1,152	0.033 (2 minutes)	38
Pretest	576	1	576	0.25 (15 minutes)	144
Survey invitation	5,400	1	5,400	0.033 (2 minutes)	180
Survey	2,700	1	2,700	0.25 (15 minutes)	675
Total					1,052

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

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, et al., ''Dietary Intake of Whole Grains,'' *Journal of the American College of Nutrition,* vol. 19, pp. 331S–338S, 2000.

3. Kantor, L.S., J.N. Variyam, J.E. Allshouse, et al., ''Choose a Variety of Grains Daily, Especially Whole Grains: A Challenge for Consumers,'' *Journal of Nutrition,* vol. 131, pp. 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 17, 2010, available at *http://supermarketnews.com/news/whole_grains_0917/#.*

6. Arvola, A., L. Lähteenmäki, M. Dean, et al., ''Consumers' Beliefs About Whole and Refined Grain Products in the UK, Italy and Finland,'' *Journal of Cereal Science,* vol. 46, pp. 197–206, 2007.

7. Kantor, L.S., J.N. Variyam, J.E. Allshouse, et al., ''Choose a Variety of Grains Daily, Especially Whole Grains: A Challenge for Consumers,'' *Journal of Nutrition,* vol. 131, pp. 473S–486S, 2001.

8. Marquart, L., K.L. Wiemer, J.M. Jones, et al., ''Whole Grain Health Claims in the USA and Other Efforts to Increase Whole-Grain Consumption,'' *Proceedings of the Nutrition Society,* vol. 62, pp. 151–160, 2003.

9. Drichoutis, A.C., P. Lazaridis, and R.M. Nayga, ''Consumers' Use of Nutritional Labels: A Review of Research Studies and Issues,'' *Academy of Marketing Science Review,* vol. 10.9, 2006.

10. Grunert, K.G. and J.M. Willis, ''A Review of European Research on Consumer Response to Nutrition Information on Food Labels,'' *Journal of Public Health,* vol. 15, pp. 384–399, 2007.

11. Kellogg Company. ''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.*

12. Clark, L.A. and D. Watson, ''Constructing Validity: Basic Issues in Objective Scale Development,'' *Psychological Assessment,* vol. 7(3), pp. 309–319, 1995.

Dated: February 21, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4423 Filed 2–24–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0140]

Draft Guidance for Industry on Notification to Food and Drug Administration of Issues That May Result in a Prescription Drug Shortage; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Notification to FDA of Issues that May Result in a Prescription Drug or Biological Product Shortage.'' This draft guidance relates to the Federal Food, Drug, and Cosmetic Act (FD&C Act), which requires sole manufacturers to notify FDA of a discontinuance of certain drug products and to the President's Executive Order 13588 of October 31, 2011, directing FDA to use all available administrative tools to expand the Agency's efforts to combat the problem of drug shortages. We are also requesting responsive comments from interested stakeholders on a specific question posed in this **Federal Register** document related to the draft guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 29, 2012.